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"Do No Harm or Injustice to Them": Indicting and Convicting Physicians for Controlled Substance Distribution in the Age of the Opioid Crisis

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"DO NO HARM OR INJUSTICE TO THEM"[1]: INDICTING AND CONVICTING PHYSICIANS FOR CONTROLLED SUBSTANCE DISTRIBUTION IN THE AGE OF THE OPIOID CRISIS

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[1] *Greek Medicine,* NAT'L INST. OF HEALTH, https://www.nlm.nih.gov/hmd/greek/greek_oath.html [https://perma.cc/A2AP-VAJQ] (last visited Nov. 28, 2018).

ABSTRACT

In response to the devastating impact of the opioid crisis, the Department of Justice has in recent years launched an aggressive crackdown on what it characterizes as "fraudulent prescribers" of controlled substances. Against this backdrop, physicians, prosecutors, and defense attorneys face a number of issues.

First, there is a lingering circuit court split on the issue of whether indictments against physicians and other medical professionals for illegal controlled substance distribution must allege that the physician acted "outside the usual course of professional practice and without a legitimate medical purpose." I argue that acting without a legitimate medical purpose is an element of narcotics distribution that must be alleged in indictments for both constitutional and policy reasons.

Next, there is ambiguity as to what type of conduct is considered to have no legitimate medical purpose, and the line between poor medical practice and criminal conduct is ill-defined. I argue that the statutory scheme for prosecuting physicians is vague and ineffective at providing guidance to doctors, juries, judges, and attorneys.

Finally, there is the broader question of whether physicians should be the target of limited prosecutorial funds, or whether the government should instead focus on the pharmaceutical companies whose actions lie at the heart of the opioid crisis. This comment explores the legal options for holding drug companies accountable for their role in the crisis, and argues that these options are more effective than prosecutions of individual physicians.

INTRODUCTION

On June 28, 2018, former Attorney General Jeff Sessions[2] announced "the

[2] On November 7, 2018, Jeff Sessions was forced to resign at the request of President Donald Trump. His post was briefly filled by then-Acting Attorney General Matthew Whitaker, a former federal prosecutor who touted the administration's "law and order" approach to combating the opioid crisis. *See* Peter Baker et al., *Jeff Sessions Is Forced Out as Attorney General as Trump Installs Loyalist,* N.Y. TIMES (Nov. 7, 2018), https://www.nytimes.com/2018/11/07/us/politics/sessions-resigns.html [https://perma.cc/QST3-XJRX]; *see also* Acting Attorney General Matthew Whitaker Delivers Remarks to State and Local Law Enforcement on Efforts to Combat Violent Crime and the Opioid Crisis, Des Moines, IA (Nov. 14, 2018), https://www.justice.gov/opa/speech/acting-attorney-general-matthew-whitaker-delivers-remarks-state-and-local-law-enforcement [https://perma.cc/87CU-ZCJK]. On February 14, 2019, the Senate confirmed William Barr as Attorney General. David Shortell, *William Barr Confirmed as Attorney General*, CNN (Feb. 14, 2019), https://www-m.cnn.com/2019/02/14/politics/william-barr-senate-confirmation-vote/index.html?r=https%3A%2F%2Fwww.google.com%2F [https://perma.cc/994G-C9UA]. Barr is specially connected to a tough-on-crime approach to drugs—he served as Attorney General during the height of the George H.W. Bush administration's war on drugs (which incarcerated a disproportionate amount of minorities on drug charges), and his daughter, Mary Daly, is the Trump administration's Director of Opioid Enforcement and Prevention Efforts. Colby Itkowitz, *Trump's New Top AG Pick Would Be His Daughter's Boss at Justice*, WASH. POST (Dec. 6, 2018), https://www.washingtonpost.com/politics/2018/12/06/william-barr-shares-same-hard-line-views-drug-enforcement-his-daughter-who-already-works-justice-department/?noredirect=on&utm_term=.f5a679132cb8 [https://perma.cc/SF3Y-ZLX6]. Daly and her father appear to share similar law-and-order approaches to tackling America's drug problem. *Id.*

largest health care fraud takedown operation in American history."[3] As part of this takedown, the Department of Justice charged "162 people—including 32 doctors—with the illegal distribution of opioids."[4] Attorney General Sessions noted that the "ongoing opioid crisis . . . is the deadliest drug epidemic in American history,"[5] and lamented that "[s]ome of our most trusted medical professionals look at their patients—vulnerable people suffering from addiction—and they see dollar signs."[6]

Attorney General Sessions's remarks reflect the Trump administration's hardline law-enforcement approach to combating the opioid crisis. A statement on The White House website details the administration's "aggressive and multifaceted response to opioid addiction:" "[t]he Administration is bringing its tough law-and-order approach to the drug trade" by, among other things, "cracking down on fraudulent prescribers."7 This approach to the opioid crisis includes assigning twelve Assistant United States Attorneys to investigate opioid-related healthcare fraud in "opioid 'hot-spots,'" creating a Medicare Fraud Strike Force to charge people, including doctors, with prescribing and distributing opioids, and "initiat[ing] a surge to focus on pharmacies and prescribers who are dispensing unusual or disproportionate amounts of drugs, intensifying the fight against prescription drug diversion."8

Statistics confirm Attorney General Sessions's assertion that the opioid crisis has had a deadly and devastating effect on American lives. Opioids kill more than 115 people every day in America.[9] In 2017, there were over 72,000 deaths related to drug overdoses in the United States, two-thirds of which involved opioids.[10] Drugs caused more American deaths in 2017 than guns, car crashes, or HIV/AIDS have ever caused in a single year.[11] Americans, particularly those in the rural areas that have been hit hardest by the opioid epidemic, have been forced to confront this widespread problem, often when tragic overdoses mar their own communities and families. An October 2018 poll found that rural Americans see opioid addiction as

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[3] Attorney General Sessions Delivers Remarks Announcing National Health Care Fraud and Opioid Takedown, Washington, D.C. (June 28, 2018), https://www.justice.gov/opa/speech/attorney-general-sessions-delivers-remarks-announcing-national-health-care-fraud-and [https://perma.cc/K8QM-4TCQ] [hereinafter *Attorney General Sessions Remarks*].

[4] *Id.*

[5] *Id.*

[6] *Id.*

[7] *How We Will Win the War on Opioids*, THE WHITE HOUSE, https://www.whitehouse.gov/articles/will-win-war-opioids/ [https://perma.cc/2TB5-5H37] (last visited November 28, 2018).

[8] *Id.*

[9] *Opioid Overdose Crisis*, NATIONAL INSTITUTE ON DRUG ABUSE, https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis#one [https://perma.cc/TZF8-FFJJ] (last updated Jan. 2019).

[10] German Lopez, *2017 Was the Worst Year Ever for Drug Overdose Deaths in America*, VOX (Aug. 16, 2018, 2:00 PM), https://www.vox.com/science-and-health/2018/8/16/17698204/opioid-epidemic-overdose-deaths-2017 [https://perma.cc/HA7R-WGW5] (citing *Provisional Drug Overdose Death Counts*, NATIONAL CENTER FOR HEALTH STATISTICS, https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm [https://perma.cc/Q8S2-3UV4] (last visited Nov. 28, 2018)).

[11] *Id.*

one of the biggest problems their communities face, matched only by their fears about the lagging rural economy.[12] In the same poll, well over half of young rural Americans said they knew someone who has struggled with opioid addiction.[13]

While nearly everyone agrees that opioid addiction is a critical problem facing the country today, there appears to be a disconnect between the origins of the opioid crisis and the government's approach to solving it. Some argue that "[w]hile prosecutions do not necessarily reduce the number of Americans addicted to opioids, 'these cases are important because they push more people to seek treatment.'"[14] Yet even the federal government acknowledges that the opioid crisis did not originate with doctors, but rather with "pharmaceutical companies," who "reassured the medical community that patients would not become addicted to prescription opioid pain relievers."[15] "[H]ealthcare providers began to prescribe them at greater rates," which "subsequently led to widespread diversion and misuse of these medications before it became clear that these medications could indeed be highly addictive."[16] The National Institute on Drug Abuse points to a number of factors that acted in concert to cause the opioid crisis: "a healthcare system that sought to minimize pain and suffering" and which taught physicians that their patients would not become addicted to pain medication; "a massive flood of heroin in the 2000s from Mexico;" and the lacing of heroin with powerful and deadly synthetic opioids.[17] America became all the more susceptible to opioids with "the gradual decline of economic power in parts of the country that were once the lifeblood of the economy."[18]

Meanwhile, there are estimated to be over twenty-five million Americans suffering from chronic pain in America, many of whom, for better or worse, have been led by the healthcare system to rely on opioids to provide needed pain relief.[19] However, as opioid addiction reaches crisis levels, people suffering from chronic pain have reported being rapidly tapered off of opioids or turned away altogether by doctors who fear prosecution for inappropriate prescribing.[20] In the words of one Oregon doctor: "I will not treat chronic pain. Period . . . [t]here is too much risk involved."[21] With doctors fearful of treating patients who depend on opioids, many

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[12] Joe Neel & Alison Kodjak, *NPR Poll: Rural Americans Are Worried About Addiction and Jobs, But Remain Optimistic*, NPR (Oct. 16, 2018, 5:01 AM), https://www.npr.org/sections/health-shots/2018/10/16/656900971/npr-poll-rural-americans-are-worried-about-addiction-and-jobs-but-remain-optimis [https://perma.cc/QT7Y-XHP4].

[13] *Id.*

[14] Kate Benner, *Snaring Doctors and Drug Dealers, Justice Dept. Intensifies Opioid Fight*, N.Y. TIMES (Aug. 22, 2018), https://www.nytimes.com/2018/08/22/us/politics/opioids-crackdown-sessions.html [https://perma.cc/R2SS-Y56N].

[15] *Opioid Overdose Crisis*, *supra* note 9.

[16] *Id.*

[17] Krishnadev Calamur, *An 'Overprescription of Opioids' That Led to a Crisis,* THE ATLANTIC (June 23, 2018), https://www.theatlantic.com/health/archive/2018/06/opioid-epidemic/563576/ [https://perma.cc/Z446-SUJF].

[18] *Id.*

[19] Brianna Ehley, *How the Opioid Crackdown is Backfiring*, POLITICO (Aug. 28, 2018), https://www.politico.com/story/2018/08/28/how-the-opioid-crackdown-is-backfiring-752183 [https://perma.cc/LTN7-KT5W].

[20] *Id*.

[21] *Id.*

patients have turned to street drugs to ease their pain–some even contemplating suicide.[22] One patient, suffering from both the lingering, excruciating pain of a decades-old motorcycle crash as well as opioid-withdrawal symptoms, created a plan to kill himself when his doctor would no longer prescribe opioids, stating that "[his] pain exceeded [his] ability to handle it."[23]

Against this complicated backdrop, there are a number of issues that add to the uncertainty doctors face when contemplating their potential criminal liability for prescribing opioids. First, there is a lingering circuit court split in a small but crucial aspect of prosecuting doctors for drug distribution. Circuit courts are divided on the issue of whether indictments against medical professionals for illegal controlled substance distribution must allege that the medical professional acted outside the usual course of professional practice and without a legitimate medical purpose (or some variation on that language). Some courts view acting without a legitimate medical purpose as an essential element of the crime that must be alleged in an indictment in order to comply with the standards of the Fifth and Sixth Amendments, while others believe that acting for a legitimate medical purpose is an exception to the general prohibition on controlled substance distribution that does not need to be negated in an indictment.

Next, there is great ambiguity as to what type of conduct is considered outside the usual course of professional practice and without a legitimate medical purpose. Doctors have little guidance on the line between adequate care for their patients' individual health needs and criminal liability for unlawful drug distribution. While the Center for Disease Control and Prevention has released guidelines for prescribing opioids for chronic pain, these guidelines have been criticized by physicians' groups, including the American Medical Association.[24] The element of acting without a legitimate medical purpose is a question of fact that is left to the jury, which is often provided only a vague and circular sense of the element's meaning and its distinctions from the more widely understood idea of medical malpractice.[25] Critics have accused the government of "us[ing] legal ambiguity for tactical advantage" and have warned that the government "will not readily clarify lines it expects doctors to follow at their peril."[26]

Part I of this Comment explores the constitutional right to an indictment by a grand jury in felony cases, and the requirement that those indictments allege each element of the charged crime. Next, it examines the statutory framework for illegal controlled substance distribution. It then lays out the viewpoints of the various

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[22] *Id.*

[23] *Id.*

[24] *What Physicians Are Saying About the New CDC Opioid Guidelines,* AMA WIRE (Mar. 16, 2016), https://wire.ama-assn.org/delivering-care/what-physicians-are-saying-about-new-cdc-opioid-guidelines [https://perma.cc/GV24-3QUQ].

[25] *See, e.g.*, United States v. Volkman, 979 F.3d 377, 388 (6th Cir. 2015) ("This case is not about whether the defendant acted negligently or whether he committed malpractice. Rather, in order for you to find the defendant guilty, you must find that the government has proved to you beyond a reasonable doubt that the defendant's action was not for a legitimate medical purpose in the usual course of professional practice.").

[26] Harvey Silverglate, *When Treating Pain Brings a Criminal Indictment*, THE WALL STREET J. (June 12, 2015), https://www.wsj.com/articles/when-treating-pain-brings-a-criminal-indictment-1434148923 [https://perma.cc/U66Y-GFLS].

circuits that have weighed in on the issue: first looking to those that have held that acting without a legitimate medical purpose is an *element* of the crime that must be charged in an indictment against a doctor, and then to those that have held that acting with a legitimate medical purpose is an *exception* that the government does not need to allege in an indictment. It next examines petitions for writs of certiorari on this issue. Finally, Part I argues that indictments against doctors must in fact allege that medical professionals accused of controlled substance distribution acted outside the usual course of professional practice and without a legitimate medical purpose, for both constitutional and policy reasons.

Part II explores the substance of the "without a legitimate medical purpose" element. It first looks to how the element has been defined, the wide latitude given to juries in deciding this issue, and the broad range of conduct that has fallen into this nebulous element. It explores the criticism levied towards this element for being impossibly vague, difficult to clarify, and ineffective at providing guidance to doctors, juries, judges, and attorneys as to when conduct crosses the line into criminality. This Part looks particularly at the element's effect on elderly and rural physicians, before offering some solutions to the problems with defining this element.

Finally, Part III addresses alternative means of addressing the opioid crisis. It first explores the origins of the opioid crisis, namely, the pharmaceutical companies who encouraged doctors to prescribe opioids despite knowledge of the substantial risks these drugs entail, and the distributors who funneled these drugs into American homes despite knowing about their strong potential for misuse. Then, it looks to the various strategies that have been put into place to hold these companies accountable. Finally, it argues that these options are more effective than prosecutions of individual physicians.

I. ISSUES WITH INDICTMENTS OF DOCTORS FOR CONTROLLED SUBSTANCE DISTRIBUTION

A. Background

On April 12, 2018, seventy-one-year-old Dr. Joseph Olivieri was arrested in the Southern District of New York and charged with one conspiracy count and three substantive counts of controlled substance distribution.[27] Federal prosecutors alleged that Dr. Olivieri had improperly prescribed testosterone to an undercover N.Y.P.D. agent who, according to the agent, had normal testosterone and simply told Dr. Olivieri he wanted to have larger muscles.[28] On the day of his arrest, Dr. Olivieri appeared before a federal magistrate judge, who released the doctor on a number of bail conditions, including a condition that he could not prescribe any medicines or pharmaceuticals.[29] That condition was subsequently modified to prevent Dr. Olivieri

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[27] *See* Criminal Docket for Case 1:18-cr-00316-PAC, United States v. Olivieri (S.D.N.Y. 2018).

[28] Complaint at 5, United States v. Olivieri, 1:18-cr-00316-PAC (S.D.N.Y. Apr. 9, 2018), ECF No. 1; Letter from Julia Gatto, Esq., to Hon. Paul A. Crotty, *Olivieri*, 1:18-cr-00316-PAC (S.D.N.Y.) (May 14, 2018), ECF No. 19.

[29] *See* Bail Disposition, *Olivieri*, 1:18-cr-00316-PAC (S.D.N.Y. Apr. 12, 2018), ECF No.5.

only from prescribing "controlled substances,"[30] however, the damage to Dr. Olivieri's practice was already done.

Dr. Olivieri had specialized in treating predominantly gay men diagnosed with HIV and AIDs since the 1980s.[31] Many of these men had grown to rely on him to refill their needed prescriptions.[32] However, as a result of the criminal charges against him, Dr. Olivieri was quickly suspended by his employer, leaving him with little income or future job prospects while his patients scrambled to fill their needed prescriptions.[33] As a result of the "dire financial straits" the loss of his employment put him in, the physician was forced to sell his New York home.[34]

This chain of events, which left an elderly doctor who had devoted his career to treating HIV/AIDs victims without a home or job, all occurred after an indictment which failed to accuse the physician of prescribing without a legitimate medical purpose, and prior to any finding or plea of guilt.[35] While it is clear from the Complaint filed on April 9, 2018 that the United States Attorney's Office for the Southern District of New York believed that Dr. Olivieri had improperly prescribed testosterone to an undercover NYPD officer, the indictment endorsed by the grand jury made no mention of the fact that Dr. Olivieri was a physician, or that he was authorized by the Attorney General to prescribe controlled substances.[36] Dr. Olivieri's indictment alleged only that he "intentionally and knowingly distributed, dispensed, and possessed with intent to distribute controlled substances, in violation of Title 21, United States Code, Section 841(a)(1)."[37] In other words, Dr. Olivieri was indicted, arrested, forbidden from prescribing controlled substances, and subsequently suspended from his job treating HIV-positive men based on an indictment that alleged only that he intentionally prescribed controlled substances—an act that Dr. Olivieri was authorized to perform and which millions of physicians perform every day in order to supply their patients with needed medications.[38]

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[30] *See* Endorsed Letter as to Joseph Olivieri addressed to Magistrate Judge Ona T. Wang from Julia Gatto, Esq. (Signed by Magistrate Judge Ona T. Wang on 4/18/2018), *Olivieri*, 1:18-cr-00316-PAC (S.D.N.Y. Apr. 18, 2018), ECF No. 12.

[31] Letter from Julia Gatto, Esq., to Hon. Paul A. Crotty, *Olivieri, supra* note 28.

[32] *Id.*

[33] *Id.*

[34] Letter from Julia Gatto, Esq., to Hon. Paul A. Crotty, *Olivieri*, 1:18-cr-00316-PAC (S.D.N.Y. Oct. 10, 2018), ECF No. 53.

[35] *See* Indictment of Joseph Olivieri, Olivieri, 1:18-cr-00316-PAC (S.D.N.Y. May 1, 2018), ECF No. 13. The physician was re-indicted on August 23, 2018 in a superseding indictment that included the previously omitted element. Superseding Indictment at 2, Olivieri, 1:18-cr-00316-PAC (S.D.N.Y. Aug. 23, 2018), ECF No. 41.

[36] *See* Indictment of Joseph Olivieri, *supra* note 35; Complaint, Olivieri, 1:18-cr-00316-PAC (S.D.N.Y. Apr. 9, 2018), ECF No. 1.

[37] Indictment of Joseph Olivieri at 2, Olivieri, 1:18-cr-00316-PAC (S.D.N.Y. May 1, 2018), ECF No. 13.

[38] In the Superseding Indictment filed on August 23, 2018, Dr. Olivieri was charged with substantive and conspiracy counts of prescribing additional controlled substances, including opioids. Superseding Indictment at 1-8, Olivieri, 1:18-cr-00316-PAC (S.D.N.Y. Aug. 23, 2018), ECF No. 41. He pled guilty to one count of conspiracy to unlawfully distribute controlled substances on May 2, 2019. Transcript of Proceedings as to Joseph Olivieri re: Plea held on 5/2/19 before Judge Paul A. Crotty, Olivieri, 1:18-cr-00316-PAC (S.D.N.Y. May 2, 2019), ECF No. 77. His sentencing has been postponed pending a number of serious health issues. *See* Letter

1. *The Right to an Indictment by a Grand Jury*

The Fifth Amendment to the United States Constitution requires that "[n]o person shall be held to answer for a[n] . . . infamous crime, unless on a presentment or indictment of a Grand Jury."[39] Furthermore, the Sixth Amendment requires that "in all criminal prosecutions, the accused shall enjoy the right . . . to be informed of the nature and cause of the accusation."[40] The Fifth and Sixth Amendments together stand for the "substantial right" of a defendant accused of a felony "to be tried *only* on charges presented in an indictment returned by a grand jury,"[41] so as to protect defendants from being "convicted on the basis of facts not found by, and perhaps not even presented to, the grand jury which indicted him.[42] Indictments meet this constitutional standard by "contain[ing] every element of the offense intended to be charged."[43] Indictment by a grand jury "serves the 'dual function of determining if probable cause exists to believe that a crime has been committed and of protecting citizens against unfounded criminal prosecutions.'"[44] The Supreme Court described the grand jury as "a protective bulwark standing solidly between the ordinary citizen and an overzealous prosecutor."[45]

Federal grand jury pools, like federal trial jury pools, are made up of U.S. citizens over the age of eighteen living within the federal district court's geographical region.[46] These potential jurors are then screened to ensure they speak English, are mentally and physically competent, and have never been convicted of a felony.[47] A federal grand jury is charged with making the ultimate determination that there is probable cause that a crime has been committed, and prosecutors can subpoena witnesses and documents to provide the grand jury with evidence of a crime.[48] While in practice there is a common belief that grand juries are so influenced by prosecutors that "you can get a grand jury to 'indict a ham sandwich,'" the federal grand jury still retains the constitutionally-granted ability to make the ultimate decision as to whether or not to indict an individual who is under investigation for a federal

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from Julia Gatto, Esq., to Hon. Paul A. Crotty, Olivieri, 1:18-cr-00316-PAC (S.D.N.Y. Oct. 15, 2019), ECF No. 105.

[39] U.S. CONST. amend. V. The Grand Jury Clause applies to any crime punishable by death or more than one year of imprisonment. *See, e.g.* United States v. Coachman, 752 F.2d 685, 689 n.24 (D.C. Cir. 1985); *see also* Fed. R. Crim. P. 7(a)(1).

[40] U.S. CONST. amend. VI.

[41] Stirone v. United States, 361 U.S. 212, 217 (1960) (emphasis added).

[42] Russell v. United States, 369 U.S. 749, 770 (1962).

[43] Cochran v. United States, 157 U.S. 286, 290 (1895).

[44] Tony Onorato & Tymour Okasha, *Twenty-Ninth Annual Review of Criminal Procedure: Introduction and Guide for Users: II. Preliminary Proceedings: Grand Jury*, 88 GEO. L.J. 1078, 1078–79 (2000).

[45] United States v. Dionisio, 410 U.S. 1, 17 (1973).

[46] Peter A. Joy*, The Grand Jury's Role in American Criminal Justice, Explained*, THE CONVERSATION (Aug. 7, 2017), https://theconversation.com/the-grand-jurys-role-in-american-criminal-justice-explained-82197 [https://perma.cc/J2N2-9UNQ].

[47] *Id.*

[48] *Id.*

felony.[49]

2. The Statutory Scheme for Drug Distribution

Street heroin dealers, physicians struggling to walk the line between adequate treatment and over-prescription of federally controlled substances,[50] and pill-mills churning out thousands of illicit opioid prescriptions can all be charged under the same federal statute. 21 U.S.C. section 841(a)(1) states that "[e]xcept as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally . . . to manufacture, distribute or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance."[51] However, 21 U.S.C. section 822(b) empowers the Attorney General to create a registration system for medical professionals who, once registered, are authorized to distribute controlled substances.[52] The Attorney General regulates these medical professionals via 21 C.F.R section 1306.04, which notes that controlled substances may only be prescribed "for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice."[53] In *United States v. Moore*, the governing Supreme Court case regarding the prosecution of physicians under section 841, the Court made it clear that "registered physicians can be prosecuted under section 841 when their activities fall outside the usual course of professional practice,"[54] despite the fact that "[a] strict reading of [the statutory scheme] would authorize a physician to prescribe drugs freely and without medical reason so long as the physician is registered with the Attorney General."[55] Finally, 21 U.S.C. section 885(a)(1) states that "[i]t shall not be necessary for the United States to negative any exemption or exception set forth in this subchapter in any . . . indictment . . . and the burden of going forward with the evidence with respect to any such exemption or exception shall be upon the person claiming its benefit."[56]

3. The Circuit Court Split

Circuit courts are split as to the essential elements of controlled substance distribution under section 841(a)(1) when the defendant is a medical professional registered with the Attorney General.[57] The issue dividing the circuit courts is whether, for defendant-physicians, distribution outside the usual course of

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[49] Ben Zimmer, *'Indict a Ham Sandwich' Remains on the Menu for Judges, Prosecutors*, WALL ST. J. (June 1, 2018), https://www.wsj.com/articles/indict-a-ham-sandwich-remains-on-the-menu-for-judges-prosecutors-1527863063 [https://perma.cc/8Y6M-CVW4]; Joy*, supra* note 46.

[50] 21 C.F.R. § 1308 (2018). Federally controlled substances include opioids as well as many non-opioid medications, such as the testosterone prescribed by Dr. Olivieri. *See id.*

[51] 21 U.S.C. § 841(a)(1) (2018).

[52] 21 U.S.C. § 822(b).

[53] 21 C.F.R. § 1306.04.

[54] United States v. Moore, 423 U.S. 122, 124 (1975).

[55] United States v. Outler, 659 F.2d 1306, 1309 (5th Cir. Unit B Oct. 1981).

[56] 21 U.S.C. § 885(a)(1).

[57] *See* United States v. Quinones, 536 F. Supp. 2d 267, 270 n.1 (E.D.N.Y 2008); *see also* Leonard B. Sand et al., *3 Modern Federal Jury Instructions*, Instruction 56.02 (noting that "there is a split in the circuits as to whether the government must allege that the defendant dispensed the drugs other than for a legitimate medical purpose and not in the usual course of medical practice").

professional practice and without a legitimate medical purpose is an element of the crime that must be set forth in the indictment, or whether a registered physician operating within the usual course of professional practice is an exception that, per section 885(a)(1), the government is not required to "negative" in an indictment.[58]

B. Circuits Holding that Acting Without a Legitimate Medical Purpose is an Element

1. The Fifth Circuit

In *United States v. Outler*, the Fifth Circuit directly and expansively addressed the issue of whether acting without a legitimate medical purpose is an element of drug distribution by physicians or an exception.[59] The physician in that matter prescribed controlled substances to undercover agents after performing minimal physical examinations and after the agents stated that the drugs would be used recreationally and sold to others.[60] The indictment against the physician contained fifteen "virtually identical" counts which each used language similar to count one:

> That on or about October 12, 1979, in the Macon Division of the Middle District of Georgia, and within the jurisdiction of this Court, James E. Outler did unlawfully and intentionally distribute, dispense, and caused to be distributed and dispensed, a quantity of benzphetamine in the form of Didrex tablets, a Schedule III drug, by means of a prescription to Rita Bragg, in violation of 21 United States Code, Section 841(a).[61]

At trial, the jury instructions included the element of prescribing without a legitimate medical purpose and the prosecution introduced evidence to sufficiently prove this element beyond a reasonable doubt. However, the Fifth Circuit held that "the lack of a legitimate medical reason is an essential element of [a physician prescribing drugs in violation of 21 U.S.C. section 841(a)], and therefore must be alleged in the indictment."[62]

The court concluded that the lack of a legitimate medical reason was an element that "embodie[d] the culpability of the offense" because "[w]ithout behavior beyond professional practice, there is no crime."[63] While the court acknowledged the government's argument that the statutory construction of the Controlled Substances Act seems to treat the presence of a legitimate medical purpose as an exception to the general prohibition from distributing controlled substances, it went on to note that, despite the general rule that statutory exceptions need not be alleged in an indictment, "in rare instances, an exception can be so necessary to a true definition

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[58] Quinones, 536 F. Supp. 2d at 270, n.1.

[59] Outler was decided by Unit B of the former Fifth Circuit during the transitional period that occurred while dividing the former Fifth Circuit into the new Fifth Circuit and the Eleventh Circuit. The Eleventh Circuit has since overruled Outler, *see* United States v. Steele, 147 F.3d 1316 (11th Cir. 1998) (en banc) (discussed *infra*), but Outler remains binding precedent in the Fifth Circuit.

[60] Outler, 659 F.2d at 1308.

[61] *Id.*

[62] *Id.* at 1309.

[63] *Id.*

of the offense that the elements of the crime are not fully stated without the exception. . . . We believe this to be the case whenever a physician is charged with prescribing drugs in violation of 21 U.S.C. § 841(a)."[64] Otherwise, the court noted,

> a grand jury properly could return an indictment against any doctor for prescribing a controlled drug, and the doctor always would have the burden at trial of proving the prescription was based on a legitimate medical need. The effect of this scheme would be a presumption that every physician who prescribes a drug does so without a legitimate medical reason. We do not believe Congress intended this result.[65]

The court finally noted that the requirement that a grand jury indictment must allege each element of an offense protects both the Sixth Amendment right of a defendant to be informed of the nature of the charges against him, and the Fifth Amendment right to an indictment by a grand jury in serious crimes.[66] Even where a physician is actually aware of the fact that he is alleged to have acted without a legitimate medical purpose, as he almost certainly will be when he is being charged with controlled substance distribution, "[t]o allow . . . a subsequent guess as to what was in the minds of the grand jury at the time they returned the indictment would deprive the defendant of a basic protection which the guarantee of the intervention of a grand jury was designed to secure."[67]

2. The Ninth Circuit

In *United States v. King*, a defendant physician charged with distributing cocaine was similarly charged with conspiracy and substantive counts of controlled substance distribution by an indictment that failed to allege that he was a practitioner distributing narcotics without a legitimate medical purpose.[68] The Ninth Circuit concluded that "lack of authorization to distribute or dispense controlled substances is an element of the crime," which must be charged in the indictment, and found the indictment against the defendant lacking because even "[t]he most liberal reading of the indictment does not reflect an allegation that [the defendant] acted outside the scope of the medical exception."[69] The court relied on its holding in *United States v. Black*,[70] where it noted that "[i]t is not 'more likely than not' that medical practitioners registered to dispense controlled substances do so illegitimately and are guilty of a criminal act; common experience . . . dictates precisely the opposite conclusion."[71]

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[64] *Id.* at 1309-1310, 1309 n.3.
[65] *Id.* at 1309 n.3.
[66] *Id.* at 1310.
[67] *Id.* at 1311 (quoting Russell v. United States, 369 U.S. 749, 770 (1962)).
[68] United States v. King, 587 F.2d 956, 963 (9th Cir. 1978).
[69] *Id.*
[70] United States v. Black, 512 F.2d 864, 871 (9th Cir. 1975).
[71] It should be noted that the Ninth Circuit has deemed an indictment acceptable when it did not explicitly allege absence of authorization, but did allege that a pharmacist possessed pseudoephedrine that he knew and had reasonable cause to believe would be used to make methamphetamine, reasoning that the indictment sufficiently informed the defendant that he was charged with criminal conduct not covered by the exception for legitimate medical use. United States v. Jae Gab Kim, 298 F.3d 746, 748, 750 (9th Cir. 2002).

3. The Fourth and Tenth Circuits

The Fourth and Tenth Circuits have reached less expansive conclusions, and they have not spoken directly to the issue of what elements must be alleged in an indictment. However, both have held that when a physician is charged with controlled substance distribution in violation of §841(a), the government must prove: "(1) that the defendant distributed or dispensed a controlled substance; (2) that the defendant acted knowingly and intentionally; and (3) that the defendant's actions were not for legitimate medical purposes in the usual course of his professional medical practice or were beyond the bounds of medical practice."[72]

C. Circuits Holding that Acting Without a Legitimate Medical Purpose is an Exception that Need Not be Alleged in an Indictment

1. The Eleventh Circuit

In *United States v. Steele,* a pharmacist was indicted for dispensing controlled substances in violation of section 841(a).[73] The indictment charged four separate counts, all of which were identical except for the controlled substances named in them. Count one read:

> That from on or about July 1, 1993, and continuously thereafter, up to and including on or about November 2, 1993, in the Northern District of Florida, the defendant, William O. Steele, did knowingly and intentionally dispense hydromorphone hydrochloride, a schedule II controlled substance, commonly known as Dilaudid, in violation of Title 21, United States Code, Section 841(a)(1).[74]

The Eleventh Circuit, in perhaps the most firm ruling of all the circuit courts on this side of the issue, held that "an indictment of a practitioner for unlawfully dispensing drugs need not aver that it was done outside the course of professional practice."[75] The court looked specifically to section 855(a)(1), and, based on the provision's "explicit and unambiguous" language, held that it meant that "an indictment charging a violation of § 841(a) need not negate the course of professional practice exception."[76] While the court noted the defendant's point that "Congress could not have meant what it said in § 885(a)(1), because that would mean prosecutors could indict each and every pharmacist and doctor in the country for simply carrying out their professional duties," the court wrote that they "seriously doubt that the Department of Justice would tolerate the continued employment of any prosecutor" who would indict such cases.[77] "Busy government prosecutors"

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[72] United States v. Hurwitz, 459 F.3d 463, 475 (4th Cir. 2006) (internal citations omitted); *see also* United States v. Varma, 691 F.2d 460, 462 (10th Cir. 1982) (holding that the government must prove "(1) That defendant distributed a controlled substance; (2) That he acted intentionally or knowingly; and (3) That defendant prescribed the drug without a legitimate medical purpose outside the usual course of professional practice.").

[73] United States v. Steele, 147 F.3d 1316, 1317 (11th Cir. 1998).

[74] *Id.*

[75] *Id.*

[76] *Id.* at 1318-19.

[77] *Id.* at 1319.

would not want to indict cases they are certain to lose at trial, according to the court.[78] The court finally noted that Congress alone has the power to define crimes and defenses, and that Congress has said that the legitimate medical purpose exception is a defense, not an element.[79]

2. The Third Circuit

In *United States v. Polan*, a physician was indicted and convicted of one conspiracy count and thirty-one substantive counts of distributing oxycodone in violation of 21 U.S.C. section 841(a)(1) and (b)(1)(C). The physician was charged with writing prescriptions for individuals who he was aware would turn over the prescribed drugs to a co-conspirator, who subsequently would sell the drugs or barter them for sexual favors.[80] The defendant raised a post-conviction argument that the indictment failed to charge an essential element of the offense of illegal drug distribution.[81] Because the challenge to the indictment was tardy, the indictment was construed in favor of the government.[82]

The Third Circuit relied on the 1922 Supreme Court case *McKelvey v. United States*, where the court concluded that it was

> a settled rule . . . that an indictment or other pleading founded on a general provision defining the elements of an offense, or of a right conferred, need not negative the matter of an exception made by a proviso or other distinct clause, whether in the same section or elsewhere, and that it is incumbent on one who relies on such an exception to set it up and establish it.[83]

The court stated that this rule from *McKelvey* was "codified" in 21 U.S.C section 885(a)(1).[84] It then held that there are three elements to illegal drug distribution by a physician: "the physician must (1) knowingly or intentionally (2) distribute (3) a controlled substance," and that allegations that the drug distribution was not authorized by the Attorney General are not required in an indictment due to section 885(a)(1) and *McKelvey*.[85]

The court noted that the Ninth and Fifth Circuits did not address section 885(a)(1), "which is clearly controlling unless its application in this situation is unconstitutional," and that the arguments by those circuits were therefore unpersuasive.[86] It addressed the *Outler* court's suggestion that an exception may be essential enough to a crime that it becomes an element of the crime, stating that it was "not persuaded by this argument because essentially the same argument can be made with respect to every statutory exception."[87] The court held that it could not refuse to follow section 885(a)(1) and *McKelvey* "simply because it could in theory

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[78] *Id.*
[79] *Id.* at 1320.
[80] United States v. Polan, 970 F.2d 1280, 1281-82 (3d Cir. 1992).
[81] *Id.* at 1282.
[82] *Id.*
[83] McKelvey v. United States, 260 U.S. 353, 357 (1922).
[84] Polan, 970 F.2d at 1282.
[85] *Id.*
[86] *Id.* at 1283.
[87] *Id.* at 1283 n.1.

result in abusive indictments of physicians—an eventuality that apparently has not occurred in the 22 years since this provision was enacted."[88]

3. The Seventh Circuit

In *United States v. Roya*, the defendant-physician was convicted of twenty-four counts of controlled substance distribution for prescribing stimulant drugs to undercover agents after minimal examinations and despite the agents' statements indicating that they were sharing the drugs with others.[89] All counts of the indictment alleged that the defendant either "dispensed or . . . attempted to dispense controlled substances 'pursuant to a prescription not written in the course of professional practice.'"[90] However, the defendant-physician argued that the indictment was "vague, uncertain, and failed to inform him of the nature and cause of the accusations against him with the certainty required by law" because, among other things, "(1) it failed to cite the regulation, the violation of which was the essence of the charge against him, [and] (2) it failed to state an element of the offense which was included in the regulation."[91] The defendant took issue with the fact that the indictment used the "not written in the course of professional practice" language without citing to the Attorney General's regulation containing this language, 21 C.F.R. section 1304.04(a), and that it did not contain the "without a legitimate medical purpose" language also found in 21 C.F.R. section 1306.04(a).[92]

The Seventh Circuit disagreed with the defendant's characterization of the indictment and concluded that the indictment "clearly stated the essential elements of the offense and that the disputed language merely clarified the grand jury's position that the accused did not fit within an exemption to the charged offense."[93] The court wrote that

> the disputed language, in our opinion, was not essential to a properly drawn indictment. An indictment founded on a general provision of a statute need not negative an exception made by a proviso or other distinct clause, whether in the same section or elsewhere. Addition of such language, therefore, should not render an indictment defective.[94]

The court noted that inclusion of this language was not necessary to "properly charge[] this defendant, in a manner making the charge sufficiently clear to him, that he had dispensed in a manner not exempted under the statute."[95] According to the court, the indictment did not "render[] the defendant unable to prepare a defense adequately, to have caused him surprise at trial, or to have placed him in double jeopardy."[96]

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[88] *Id.*
[89] United States v. Roya, 574 F.2d 386, 388-89 (7th Cir. 1978).
[90] *Id.* at 390.
[91] *Id.* at 389-90.
[92] *Id.* at 390-91.
[93] *Id.*
[94] *Id.* at 391 (citing McKelvey v. United States, 260 U.S. 353, 357 (1922); United States v. DiPietroantonio, 289 F.2d 122, 124 (2d Cir. 1961)).
[95] *Id.* at 391.
[96] *Id.*

4. The Sixth Circuit

Finally, in *United States v. Seelig*, three defendant-pharmacists appealed their convictions for distributing Valium and codeine-based cough medicine Dextropropoxyphene (both opiates) in violation of section 841(a)(1).[97] The defendants objected to the fact that the indictment failed to charge them with acting "not in the usual course of professional practice," as "pharmacists are exempt from the criminal sanctions of section 841(a)(1) if they dispense drugs in the usual course of professional practice."[98] Because the indictment alleged the date, serial number, and issuing doctors of the prescriptions in question, the court was unconcerned by the possibility that the defendants might not have enough facts to avoid being prosecuted again for the same crime.[99] In a somewhat circular opinion, the court held that because,

> [a]s a matter of law, a registered doctor is subject to the criminal penalties of section 841(a)(1) if he is not acting within the usual course of professional conduct . . . the allegation of distribution in violation of section 841(a)(1) includes the legal definition that the drugs were not . . . distributed in the usual course of professional practice.[100]

In other words, an indictment alleging illegal distribution of controlled substances incorporates the allegation that those substances were not distributed in the usual course of professional practice, even when it does not explicitly state that element.

D. Petitions for Writ of Certiorari

In many of the above cases, either the government or the individual defendant submitted a petition for writ of certiorari to the Supreme Court asking the Court to weigh in on the issue of indictments against doctors charged with illegal drug distribution.[101] For instance, defendant William Steele petitioned the Court to review the Eleventh Circuit's holding in *United States v. Steele*.[102] The question presented in Steele's petition was whether

> an indictment charging a practitioner . . . with dispensing a controlled substance in violation of Section 841(a)(1) of Title 21, United States Code, meet[s] the constitutional standards for an indictment established by the Fifth and Sixth Amendments to the United States Constitution if it fails to allege that the defendant's conduct in dispensing the controlled substance was outside the scope of professional practice?[103]

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[97] United States v. Seelig, 622 F.2d 207, 209 (6th Cir. 1980).
[98] *Id.* at 211.
[99] *Id.*
[100] *Id.*
[101] *See generally, e.g.*, Polan v. United States, 513 U.S. 1050 (1994); Outler v. United States, 455 U.S. 950 (1982); Seelig v. United States, 449 U.S. 869 (1980); Roya v. United States, 439 U.S. 857 (1978) (denying petitions for writ of certiorari).
[102] Petition for Writ of Certiorari, United States v. Steele, 147 F.3d 1316, 1319 (11th Cir. 1998) (No. 94–3139), 1999 WL 33640050 (U.S.).
[103] *Id.* at *i.

However, despite the conflicting positions of the Circuit Courts of Appeal, the Supreme Court has consistently denied certiorari petitions on this issue.[104]

E. The Circuit Courts that Require Indictments to Allege that Controlled Substance Distribution Took Place Without a Legitimate Medical Purpose and Not in the Usual Course of Professional Practice Take the Correct Approach

While the Supreme Court has repeatedly rejected petitions for writ of certiorari on the issue of indictments against doctors charged under section 841(a)(1), the severity of the opioid epidemic and the Department of Justice's subsequent crackdown on doctors prescribing opioids makes this issue newly relevant, and at some point the Court may decide to finally address the issue. Furthermore, a number of circuits have yet to conclusively rule on this issue, leaving little guidance for both federal prosecutors preparing indictments and federal district court judges ruling on motions to dismiss indictments for failure to state a claim. Courts that have not yet addressed this issue should follow the logic of the Fifth, Ninth, Fourth, and Tenth Circuits, and require that indictments against physicians for violation of section 841(a)(1) allege that the physician distributed controlled substances without a legitimate medical purpose and outside the usual course of professional practice.

The circuits that have held otherwise have leaned heavily on 21 U.S.C. section 885(a)(1) in concluding that prescription without a legitimate medical purpose need not be alleged in an indictment. According to these circuits, section 885(a)(1) reflects the clear intention of Congress that prescription without a legitimate medical purpose is an exception to, not an element of, illegal drug distribution. However, there are a number of issues with this reading of the statute.

1. Congress Cannot Relieve the Government of Its Obligation to Charge Each Element of a Crime in an Indictment, and Section 885(a)(1) Should Not Be Read to Do So

First, while

> defining criminal conduct is a task generally 'left to the legislative branch,' Congress may not manipulate the definition of a crime in a way that relieves the Government of its constitutional obligations to charge each element in the indictment, submit each element to the jury, and prove each element beyond a reasonable doubt."[105]

The Supreme Court has recognized that the legislature may label facts otherwise, but that these facts may nevertheless may be "'traditional elements' to which these safeguards were intended to apply."[106] Here, as the Fifth Circuit concluded in *Outler* (discussed *supra*), prescription without a medical purpose lies at the heart of the offense of illegal drug distribution for physicians. Congress almost certainly cannot have intended to imply that the millions of medical professionals distributing controlled substances across the country are presumptively guilty of a federal felony

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[104] *See supra* note 101 (listing cases denying certiorari).

[105] Harris v. United States, 536 U.S. 545, 557 (2002) (internal citations omitted), *overruled on other grounds by* Alleyne v. United States, 570 U.S. 99 (2013).

[106] *Id.*

unless they prove that their prescription was legitimate in a court of law.[107] While the Third Circuit feared that this reading of section 885(a)(1) would necessitate reading every statutory exception as an element, it seems plain that not all exceptions are as crucial to the definition of the crime as the exception for licensed doctors lawfully prescribing medicine.[108]

Adding to the idea that acting without a legitimate medical purpose is an element of controlled substance distribution for physicians is the undisputed fact that "lack of a legitimate medical purpose" must be proved at trial beyond a reasonable doubt. Even within circuits holding that indictments need not allege that doctors acted without a legitimate medical purpose, the United States Attorney's Office routinely urges judges to instruct juries that they cannot find physician-defendants guilty unless it is proved beyond a reasonable doubt that they acted outside the usual course of professional practice and without a legitimate medical purpose, and judges routinely honor these requests. For instance, in a case where a physician was charged with distribution of a controlled substance in the Middle District of Florida, which is located within the Eleventh Circuit, the United States Attorney's Office asked the judge to instruct the jury that:

> The Defendant can be found guilty only if all the following facts are proved beyond a reasonable doubt:
> The Defendant distributed or dispensed the controlled substances alleged in the indictment;
> The Defendant did so knowingly and intentionally, that is to say, that the Defendant knew the substance was a controlled substance under the law; and
> The Defendant did so either for no legitimate medical purpose or outside the usual course of professional practice.[109]

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[107] Controlled substances, it should be noted, range from methamphetamine and heroin to Robitussin and Lunesta. *See* 21 C.F.R. §§ 1308.11-1308.15.

[108] The Third Circuit also relies heavily on McKelvey v. United States, 260 U.S. 353 (1922), the holding of which the Court claims is the foundation of § 885(a)(1). *McKelvey* is a 100-year-old case concerning an apparent band of rouge cowboys who obstructed at gunpoint a group of sheep farmers from moving their flock across federal public lands. 260 U.S. at 354-55. The cowboys were indicted under a federal law stating that:

no person, by force, threats, intimidation, or by any fencing or inclosing, or any other unlawful means, shall prevent or obstruct, or shall combine and confederate with others to prevent or obstruct, any person from peaceably entering upon or establishing a settlement or residence on any tract of public land subject to settlement or entry under the public land laws of the United States, or shall prevent or obstruct free passage or transit over or through the public lands*: Provided, this section shall not be held to affect the right or title of persons, who have gone upon, improved or occupied said lands under the land laws of the United States, claiming title thereto, in good faith*.

260 U.S. at 356 (emphasis added). This statute, carving out a narrow exception for homesteaders sprinkled throughout hundreds of millions of acres of federal public lands, appears patently different from a statute that, taking the Third Circuit's view, would subject the over one million physicians practicing in the United States to a federal indictment unless they could prove that they were not one of a relative handful of bad actors prescribing drugs without a medical purpose.

[109] Proposed Jury Instructions at 26, United States v. Gayden¸ No. 6:16-cr-187-Orl-41TBS (M.D. Fla. June 4, 2018); *see also, e.g.*, Transcript of Jury Instructions and Verdict at 27-28, United States v. Chapman, No. 4:11-CR-22-HLM-05 (N.D. Ga. Feb. 1, 2016) ("[T]he defendant can be found guilty of the offenses charged . . . only if all of the following facts are proven beyond a

By acknowledging that acting "for no legitimate medical purpose or outside the usual course of professional practice" is a fact that must be proved beyond a reasonable doubt, the government recognizes that that fact is an element of the crime of controlled substance distribution for physicians.[110] Because there is a constitutional right that all elements of a crime must be alleged in an indictment, it logically follows that the fact that the government itself contends is an element must be alleged in criminal indictments against physicians for controlled substance distribution.

Judge Leonard Sand noted that a reading of section 885(a) that "shift[s] the burden of proving that the prescriptions were issued for a legitimate medical purpose to the defendant"—and which thereby makes authorized prescriptions an exception—"raises serious constitutional questions . . . . The most sensible and constitutionally acceptable way to read section 885 is simply as placing on a defendant physician an initial burden of production [of the fact that he is a registered medical practitioner]."[111] In *Black*, the Ninth Circuit recognized that "the government by its own evidence established that [the defendant] was a 'practitioner.'"[112] Almost inevitably, when a physician is charged with illegal drug distribution the government will produce evidence that the defendant is a medical professional, thereby satisfying the initial burden of production which then brings the "no legitimate medical purpose" element to the table. It seems likely that section 885(a) was not intended to make prescription without a legitimate medical purpose a fact that need not be alleged in an indictment, but rather, was intended to safeguard against a scenario where a defendant who was not known to be a physician by the government could claim that an indictment was improper for not alleging that the defendant acted without a legitimate medical purpose.[113] In that case, the government would not be required to affirmatively "negative" the possibility that the defendant might be a physician registered with the Attorney General. However, in the vast majority of cases against doctors, federal prosecutors are aware that the defendants are doctors, and therefore section 885(a)(1) is not relevant to these cases.

2. The Premise that Prosecutors will use Section 841(a)(1) Responsibly is Flawed

Both the Eleventh and the Third Circuits lean on the idea that even if federal

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reasonable doubt as to each count: First: That the defendant dispensed a controlled substance or caused a controlled substance to be dispensed as charged in the particular count of the indictment; Two: That the defendant acted knowingly and intentionally; and Third: That the defendant either acted outside the usual course of professional practice or acted without a legitimate medical purpose.").

[110] *See* In re Winship, 397 U.S. 358, 362 (1970).

[111] Sand, *supra* note 57, Instruction 56.18.

[112] United States v. Black, 512 F.2d 864, 867 (9th Cir. 1975).

[113] *See, e.g.*, United States v. Miranda, 494 F.2d 783, 785–87 (5th Cir. 1974) (holding that indictment did not need to allege that defendant was not authorized to distribute heroin because he, unlike a registered physician, was not included within any of the statutory categories that would allow him to distribute controlled substances lawfully); *see also* Echavarria–Olarte v. Reno, 35 F.3d 395, 399 (9th Cir. 1994) (holding that indictment did not need to charge that the defendant possessed or imported drugs "unlawfully" where "nothing in the record indicates that [the defendant] is a doctor or other person permitted to distribute or import cocaine").

prosecutors *could* indict physicians across the country, they would not pursue such cases when there would be little chance of success. This is all but certain, they claim, as "there has been no report of prosecutors running amuck" against doctors.[114] There are two issues with this logic. First, the Supreme Court has repeatedly warned that "we cannot construe a criminal statute on the assumption that the Government will 'use it responsibly.'"[115] Where the Court has had the option between relying on "the Government's discretion to protect against overzealous prosecutions" or narrowing its interpretation of a statute, it has concluded that "a statute . . . that can linguistically be interpreted to be either a meat axe or a scalpel should reasonably be taken to be the latter."[116]

The second problem with this line of reasoning is that prosecutors very well may abuse their discretion in indicting physicians. While the Third Circuit claimed that no abusive indictments of physicians have been reported since the statute's enactment, it does not appear that that court undertook a comprehensive study of physicians indicted for federal drug distribution. Even a relatively cursory inquiry into physicians acquitted on federal drug charges reveals a litany of complaints of overzealous prosecutors indicting doctors on evidence juries did not find convincing. One defense attorney, whose client was acquitted of nineteen counts of unlawful controlled substance distribution, stated:

> We believe that the jury's decision should send a message to the federal government that we cannot try to paper over the opioid crisis by scapegoating doctors who are simply trying to do their jobs in treating people with debilitating pain. The government needs to address the real problem of addiction and treatment and leave our hardworking doctors alone. Dr. Szyman worked hard to take care of his patients. And the government was wrong to interfere with that. The jury's verdict made that statement loud and clear.[117]

The Department of Justice, under the gaze of the Trump White House, has made no secret of the fact that it is zealously prosecuting physicians whom it believes

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[114] United States v. Steele, 147 F.3d 1316, 1319 (11th Cir. 1998); *see also* United Stated v. Polan, 970 F.2d 1280, 1283, 1283 n.1 (3d Cir. 1992).

[115] McDonnell v. United States, 136 S. Ct. 2355, 2372-73 (2016) (quoting United States v. Stevens, 559 U.S. 460, 480 (2010)).

[116] *Id.* at 2373 (quoting United States v. Sun-Diamond Growers of California, 526 U.S. 398, 408, 412 (1999)).

[117] *Doctor Found Not Guilty of Overprescribing Painkillers*, FOX 11 NEWS (Nov. 17, 2017), https://fox11online.com/news/local/doctor-found-not-guilty-of-overprescribing-painkillers [https://perma.cc/6AAC-AEW8]; *see also Alabama Doctor Acquitted in Rock Guitarist's Overdose Death*, U.S. NEWS.COM (May 22, 2018), https://www.usnews.com/news/best-states/alabama/articles/2018-05-22/alabama-doctor-acquitted-in-rock-guitarists-overdose-death [https://perma.cc/WUZ2-SLU4] (Defense attorney for doctor acquitted of thirteen counts of federal unlawful drug distribution "described his client as a 'good person and a good doctor' and said federal prosecutor [sic] had 'wrecked' his reputation and medical practice."); Carrie Teegardin, *Doctors and the Opioid Crisis: an AJC National Investigation*, AJC.COM (Dec. 1, 2017), https://www.ajc.com/news/public-affairs/healers-dealers/wrKUc6J0p2sz4dFi3fwXJK/ [https://perma.cc/S3YC-AQDE] (Defense attorney for physician charged with drug distribution stated that "[u]nfortunately, too often when law enforcement disagrees with how a doctor is treating his or her patients, rather than simply referring the issue to a medical board that has the ability and expertise to deal with any particular situation, they want to call it criminal conduct.").

are improperly prescribing opioids.[118] Assistant United States Attorney Bill Powell, after a recent conviction of a West Virginia physician for improper opioid distribution, stated that "[i]llegal distribution of opioids by physicians has been and continues to be a high priority for prosecution in this district . . . . Physicians who believe they can hide behind their lab coats or medical licenses, and simultaneously stoke the fires of the opioid epidemic and profit from it are sadly mistaken."[119] While in the 1990s the Third and Eleventh Circuits scoffed at the idea that prosecutors may abusively indict physicians, the complex reality of the opioid crisis has led prosecutors to aggressively pursue physicians for drug crimes. In this new reality, it is evident that the protections offered by the requirement of a grand jury indictment are all the more necessary as a check on over-zealous prosecutors.

3. Medical Professionals and Their Patients Are Particularly Harmed by Imprecise Indictments

"The power to indict is the power to destroy. For the defendant, an indictment hurts everywhere—in the family, business, and community. At the end of the road, the indictment can lead to loss of liberty and financial ruin."[120] This is particularly evident in the case of physicians indicted for drug distribution, as these medical professionals cannot make their livelihood without a medical license and the ability to prescribe controlled substances. In nearly every case of a physician charged with improper drug distribution, the state medical board has responded after either the indictment or a finding of guilt by suspending or revoking the physician's license.[121] While revoking a license post-conviction presents fewer issues, medical boards that suspend professional licenses after an indictment can gravely affect the lives of physicians and their patients while those physicians remain legally innocent. Physicians may also be subject to bail conditions preventing them from prescribing controlled substances, effectively robbing them of their ability to practice medicine even before the medical board steps in.

In Dr. Olivieri's case, for example, many of the physician's HIV-positive patients, who were "dependent on him for continuity of care and the refilling of their needed prescriptions," were left in the lurch when their doctor of many decades was suddenly stripped of his ability to provide them with medical care.[122] Dr. Olivieri's patients were at least lucky in that there are many other physicians in the New York City area. For rural patients, however, the indictment of their physician can leave them scrambling to find someone to fill their needed prescriptions. Of 378 doctors charged with controlled substance distribution (249 charged federally and 131

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[118] *See Attorney General Sessions Remarks*, *supra* note 3.

[119] *West Virginia Physician Convicted of Illegal Opioid Distribution to Patients*, U.S. ATTORNEY'S OFFICE N. DIST. OF W. VA. (Jan. 28, 2019), https://www.justice.gov/usao-ndwv/pr/west-virginia-physician-convicted-illegal-opioid-distribution-patients [https://perma.cc/FMK6-VABW].

[120] Carl H. Loewenson, Jr., *The Decision to Indict*, 24 LITIGATION 13, 13 (Fall 1997).

[121] Judy McKee, *"First, Do No Harm": Criminal Prosecutions of Doctors for Controlled Substances Outside of Legitimate Medical Need*, 2 NAGTRI J., 40, 44 (2017), https://www.naag.org/assets/redesign/files/nagtri-PDF/NAGTRI_Journal_May2017.pdf [https://perma.cc/6DTF-GJ49].

[122] Letter from Julia Gatto to Hon. Paul A. Crotty, *supra* note 28.

charged under the equivalent state laws), 121 specialized in family medicine—the medical practice specialty that provides the majority of care for underserved and rural populations.[123] In rural areas, the loss of even one physician can have drastic consequences on wide swaths of patients. For instance, when two rural doctors stopped prescribing opioids due to warnings from the Drug Enforcement Agency ("DEA"), roughly 230 patients were affected, several of whom committed suicide when they could not find another doctor who could help them ease their chronic pain.[124]

The dramatic loss of livelihood for physicians and, even more importantly, loss of medical treatment for underserved communities, should be avoided whenever possible. Ensuring that indictments against physicians properly allege that those physicians acted without a legitimate medical purpose does not simply satisfy an abstract (albeit important) constitutional requirement. Rather, it ensures that patients are not deprived of their medical provider unless a grand jury determines that there is probable cause to believe that the provider acted without a legitimate medical purpose.

4. Most Physicians Indicted for Controlled Substance Distribution Plead Guilty, and Guilty Pleas are Particularly Burdensome for Licensed Medical Professionals

Out of roughly 268 doctors investigated by the DEA and ultimately found guilty of either a federal or state crimes between 2003 and 2017, 222 pled guilty or no contest, while only 46 were convicted by a jury.[125] While this number is actually somewhat lower than the overall percentage of state and federal crimes that result in plea bargains,[126] the vast majority of physicians do not have the facts of their case decided by juries that finds them guilty of each element of their alleged crimes.

Because most physicians indicted for controlled substance distribution, including opioid distribution, do not make it to a jury trial, it is even more vital that each element a prosecutor is required to prove at trial be alleged in an indictment against a physician. Otherwise, a real possibility exists that a physician could be indicted for controlled substance distribution and choose strategically to plead guilty to avoid jail time—even in cases where a grand jury has not found probable cause to believe the physician acted without a legitimate medical purpose.

Guilty pleas are particularly burdensome for physicians because, as noted above, medical boards nearly always respond to a finding of a physician's guilt by revoking

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[123] McKee, *supra* note 121, at 41-42.

[124] Elizabeth Llorente, *Doctors Caught Between Struggling Opioid Patients and Crackdown on Prescriptions*, FOX NEWS (Dec. 11, 2018), https://www.foxnews.com/health/doctors-abandon-opioid-prescribing-as-state-and-federal-authorities-step-up-enforcement [https://perma.cc/9DE6-SPPC].

[125] DRUG ENFORCEMENT ADMINISTRATION, DIVERSION CONTROL DIVISION, *Cases Against Doctors*, U.S. DEPT. OF JUSTICE, https://apps.deadiversion.usdoj.gov/CasesAgainstDoctors/spring/main?execution=e1s1 [https://perma.cc/D3TM-MY2J] (last visited April 28, 2019) (calculations by author).

[126] Gaby Del Valle, *Most Criminal Cases End in Plea Bargains, Not Trials,* THE OUTLINE (Aug. 7, 2017) https://theoutline.com/post/2066/most-criminal-cases-end-in-plea-bargains-not-trials?zd=1&zi=pkwuqdf4 [https://perma.cc/ZN2W-FGUZ].

or suspending the physician's license.[127] Physicians facing an indictment for controlled substance distribution may face the choice between going to trial and risking jail time or pleading guilty to receive a favorable sentence but losing their livelihood in the process. Because an indictment against a physician can trigger an array of consequences for the physician without the facts ever reaching a jury, it is crucial that a grand jury find that there is probable cause to believe the physician acted without a legitimate medical purpose.

II. ISSUES WITH THE "WITHOUT A LEGITIMATE MEDICAL PURPOSE" ELEMENT

A. How the Element is Defined

Despite the split in authority surrounding the issue of whether the prescription without a legitimate medical purpose and outside the usual course of professional practice (the "without a legitimate medical purpose element") must be alleged in an indictment, there is little controversy over the fact that

> once evidence is presented that the defendant was a medical practitioner duly registered to dispense controlled substances, as will be in virtually every case in which a physician is prosecuted under section 841(a), the government must shoulder its normal burden of proving every element of the offense beyond a reasonable doubt.[128]

Therefore, even in circuits where the without a legitimate medical purpose element is not required to be alleged in an indictment, the jury must be instructed that "the government must prove beyond a reasonable doubt [] that the defendant prescribed (*or* dispensed) the drug other than for a legitimate medical purpose and not in the usual course of medical practice."[129] However, this element has proven to be murky and difficult to define, making it equally difficult to defend against.

"'[P]rofessional practice' . . . refers to generally accepted medical practice."[130] "The term 'professional practice' implies at least that there exists a reputable group of people in the medical profession who agree that a given approach to prescribing controlled substances is consistent with legitimate medical treatment."[131] Courts

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[127] McKee, *supra* note 121, at 44.

[128] Sand, *supra* note 57, at Instruction 56.02.

[129] Sand, *supra* note 57, at Instruction 56-18.; *see also* United States v. Hooker, 541 F.2d 300, 305 (1st Cir. 1976) (The Government has the burden of "proving that a practitioner's prescriptions were not issued for a legitimate medical purpose . . . in the usual course of . . . professional practice") (internal quotation marks omitted) (quoting United States v. Black, 512 F.2d 864, 871 (9th Cir. 1975)); Proposed Jury Instructions by USA, United States v. Feldman, (M.D. Fla. Nov. 4, 2015) (No. 8:14-cr-521-T-27AEP), 2015 WL 10568856 (Government's proposed jury instructions filed in a federal court within the Eleventh Circuit stating that "[t]he Defendant, who is a licensed medical doctor, can be found guilty of each offense charged pursuant to Section 841 . . . only if the Government has proven all of the following beyond a reasonable doubt: *First*: That the Defendant distributed, dispensed, or caused to be distributed or dispensed, the controlled substance(s) as charged; and *Second*: That at the time of the distribution or dispensing, the Defendant knew that he was distributing or dispensing a controlled substance *not for a legitimate medical purpose or not in the usual course of professional practice*" (emphasis added)).

[130] United States v. Hurwitz, 459 F. 3d 462, 479 (4th Cir. 2006).

[131] United States v. Feingold, 454 F.3d 1001, 1007, 1011 n.3 (9th Cir. 2006).

have allowed the Government to call expert witnesses to testify as to the standard of care for physicians, including the standards outlined in the American Medical Association's ("AMA") guidelines, in order to help define this element, noting that "violation of the ethical norms and regulations may be relevant to aid the jury in understanding what constitutes a legitimate medical purpose in the usual course of professional practice."[132]

However, mere medical malpractice is not enough to convict:

> A violation of the standard of care alone is *insufficient* to support the criminal conviction of a licensed practitioner under § 841(a) . . . the district court must ensure that the benchmark for criminal liability is the higher showing that the practitioner intentionally has distributed controlled substances for no legitimate medical purpose and outside the usual course of professional practice.[133]

Merely negligent prescriptions are insufficient for criminal liability. However, "[u]nder the guise of treatment a physician cannot sell drugs to a dealer nor distribute drugs intended to cater to cravings of an addict . . . . Congress did not intend for doctors to create drug 'pushers.'"[134]

B. Criticism of the Element

The line between a physician acting negligently but within the scope of professional practice and a "drug pusher" may strike a reader as unclear and circular. Doctors and defense attorneys typically agree. In 2015, prominent criminal defense attorney Harvey Silverglate penned an op-ed in the Wall Street Journal criticizing the element as "far from clear," and calling for legislators and prosecutors to either "clarify the currently indecipherable line between treating pain and unlawfully feeding drug addicts' habits, or get out of the business of policing and terrorizing physicians."[135] Silverglate claimed that "the government uses legal ambiguity for tactical advantage and will not readily clarify the lines it expects doctors to follow at

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[132] United States v. Hoffman, No. 06-CR-66-P-S, 2006 WL 3691487, at *3 (D. Me. Dec. 12, 2006); *see also* Order on Defendant's Motion in Limine to Exclude Certain Testimony of Gary Hatfield, M.D. at 2-3, United States v. Joel A. Sabean, M.D. 867 F.3d 267 (D. Me. 2018) (No. 2:15-cr-00175-GZS) (order allowing government's expert witness, a physician, to testify as to the standard of care applicable to dermatologists and the AMA Ethical Guidelines on the treatment of family members). However, expert testimony is not required to establish that a defendant acted without a legitimate medical purpose. *See* United States v. Word, 806 F.2d 658, 662-64 (6th Cir. 1986) (collecting cases).

[133] Feingold, 454 F.3d at 1007-10; *see also* United States v. Volkman, 797 F.3d 377, 388 (6th Cir. 2015) ("This case is not about whether the defendant acted negligently or whether he committed malpractice. Rather, in order for you to find the defendant guilty, you must find that the government has proved to you beyond a reasonable doubt that the defendant's action was not for a legitimate medical purpose in the usual course of professional practice."); United States v. Tran Trong Cuong, 18 F.3d 1132, 1137 (4th Cir. 1994) ("A criminal prosecution [under the CSA] requires more [than a negligence standard]—that is, proof beyond a reasonable doubt that the doctor was acting outside the bounds of professional practice, as his authority to prescribe controlled substances was being used not for treatment of a patient, but for the purpose of assisting another in the maintenance of a drug habit or of dispensing controlled substances for other than a legitimate medical purpose, i.e. the personal profit of the physician.").

[134] United States v. Collier, 478 F.2d 268, 271-72 (5th Cir. 1973).

[135] Silverglate, *supra* note 26.

their peril . . . . Drug warriors collect the scalps of doctors whom they accuse of violating the laws; they have no concern in aiding the relief of patients' suffering."[136]

Silverglate was particularly concerned with the lack of federal guidance on narcotic administration. In 2004, the DEA released a pamphlet somewhat clarifying "the line between legitimate medical practice and criminal over-prescription."[137] However, the DEA withdrew that guidance less than two months later (timed, perhaps suspiciously, with the federal prosecution of a pain physician in Virginia), leaving doctors with "no official guidance about how much OxyContin [an opioid] is enough to relieve their patients' pain, and how much could land them in prison."[138]

Since Silverglate's op-ed was published, there has been some effort to clarify the federal line between legitimate opioid prescription and criminal over-prescription. The Centers for Disease Control and Prevention ("CDC") issued its first national guidelines regarding opioid prescriptions in 2016, which addressed "1) when to initiate or continue opioids for chronic pain; 2) opioid selection, dosage, duration, follow-up, and discontinuation; and 3) assessing risk and addressing harms of opioid use."[139] However, while these guidelines were purportedly developed with "input from experts, stakeholders, the public, peer reviewers, and a federally chartered advisory committee,"[140] they have received significant criticism.

The most notable criticism of the guidelines has been from the AMA—the very group that federal prosecutors often look to in defining the contours of generally accepted professional practice for physicians. In November 2018, the AMA adopted a number of resolutions criticizing the CDC guidelines, particularly its guidance as to the maximum recommended opioid dose.[141] The AMA resolved that "some patients with acute or chronic pain can benefit from taking opioids at greater dosages than recommended by the CDC Guidelines for Prescribing Opioids for chronic pain and that such care may be medically necessary and appropriate," and further resolved that the guidelines should not be used

> as anything more than guidance, and physicians should not be subject to professional discipline, loss of board certification, loss of clinical privileges, criminal prosecution, civil liability, or other penalties or practice limitations solely for prescribing opioids at a quantitative level above the MME thresholds found in the CDC Guidelines for Prescribing Opioids.142

At an AMA meeting in November 2018, Barbara McAneny, MD, the president of the AMA, recounted a story of a patient to whom she prescribed opioids in order

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[136] *Id.*
[137] *Id.*
[138] *Id.*
[139] Deborah Dowell, MD et al., *CDC Guidelines for Prescribing Opioids for Chronic Pain*, MORBIDITY AND MORTALITY WKLY. REP. (Mar. 18, 2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fmmwr%2Fvolumes%2F65%2Frr%2Frr6501e1er.htm [https://perma.cc/XW3R-AFUC].
[140] *Id.*
[141] Pat Anson, *AMA 'Inappropriate Use' of CDC Guideline Should Stop*, PAIN NEWS NETWORK (NOV. 14, 2018), https://www.painnewsnetwork.org/stories/2018/11/14/ama-calls-for-misapplication-of-cdc-opioid-guideline-to-end [https://perma.cc/W6QE-XVZY].
[142] *Id.*

to combat the pain of metastatic prostate cancer, and who was denied by a pharmacy that relied on the CDC guidelines.143 The man attempted suicide three days later, McAneny recounted, noting that "[m]y patient suffered, in part, because of the crackdown on opioids."[144]

C. Difficulties with Clarifying the Element

Given the debate within the medical community as to the standard of care for opioid prescriptions, the without a legitimate medical purpose element seems nearly impossible to define, much less to disprove. Some courts have sought to clarify this standard by:

> [G]lean[ing] from reported cases certain recurring concomitance of condemned behavior, examples of which include the following:
>
> (1) An inordinately large quantity of controlled substances was prescribed.
>
> (2) Large numbers of prescriptions were issued.
>
> (3) No physical examination was given.
>
> (4) The physician warned the patient to fill prescriptions at different drug stores.
>
> (5) The physician issued prescriptions to a patient known to be delivering the drugs to others.
>
> (6) The physician prescribed controlled drugs at intervals inconsistent with legitimate medical treatment.
>
> (7) The physician involved used street slang rather than medical terminology for the drugs prescribed.
>
> (8) There was no logical relationship between the drugs prescribed and treatment of the condition allegedly existing.
>
> (9) The physician wrote more than one prescription on occasions in order to spread them out.145

However, courts have also noted that these factors are "not an exclusive and exhaustive list of the types of conduct by which a physician can breach the limits of legitimate medical practice" and that they do not "establish some minimum number of types of conduct that must be present to permit submission to the jury of the legitimate medical practice issue."[146] Those courts have faulted defendants for attempting to take a "mechanistic approach" to the element.[147] Furthermore, this list

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143 Pat Anson, *AMA: Patients Being Harmed by Rx Opioid Crackdown*, PAIN NEWS NETWORK (NOV. 12, 2018), https://www.painnewsnetwork.org/stories/2018/11/12/ama-patients-being-harmed-by-opioid-crackdown [https://perma.cc/69YJ-73QV].

144 *Id.*

145 United States v. Rosen, 582 F.2d 1032, 1035-36 (5th Cir. 1978) (internal citations omitted); *see also* Sand, *supra* note 57 ("For example, evidence that a doctor warns his patients to fill their prescriptions at different drug stores, or prescribes drugs without performing any physical examinations or only very superficial ones, or asks patients about the amount or type of drugs they want, may suggest that the doctor is not acting for a legitimate medical purpose and is outside the usual course of medical practice. These examples are neither conclusive nor exhaustive. They are simply meant to give you an idea of the kind of behavior from which you might conclude that a doctor was not prescribing drugs for a legitimate medical purpose and was not acting in the usual course of medical practice.").

146 United States v. Harrison, 651 F.2d 353, 355 (5th Cir. 1981).

147 *Id.*

comes from a compilation of cases where defendants were tried and convicted of the same vague law that the list seeks to clarify.

As it stands, juries are told that defendants must have acted more than negligently in prescribing medications, to the point where no reputable group of physicians would find that the prescription had a legitimate medical purpose. However, when it comes to opioid prescriptions, there appears to be little consensus as to what constitutes a legitimate medical purpose. The CDC has promulgated guidelines for opioid prescriptions, but these guidelines have been criticized by the AMA. Meanwhile courts have allowed the government to present expert witnesses to testify as to the standards governing medical practices, despite the fact that a violation of professional standards alone is, at least in theory, not enough to impose criminal liability on doctors. And, while courts have attempted to provide examples of the type of conduct that is outside the course of professional practice, physicians are warned that these examples are not exhaustive. Against this backdrop, Silverglate's fear that the vague standard for acting without a legitimate medical purpose "puts physicians in great legal jeopardy, and too often leaves their patients to suffer needlessly" appears to remain well-founded.[148]

D. Effect on Elderly and Rural Physicians

These vague standards are particularly harmful for older or rural physicians, who are often overburdened with patients and not up to speed on the latest in medical ethics and best practices. Of the 378 physicians charged with controlled substance distribution under federal law or equivalent state laws between 2006 and 2016, over forty percent were over the age of sixty.[149] These physicians, who admittedly may not follow best practices in prescribing controlled substances, may end up convicted of a federal felony for what is ultimately poor, but non-criminal, medical judgment. For instance, Dr. Joel A. Sabean, a 69-year-old dermatologist from Falmouth, Maine, was convicted and sentenced to two years in prison for, among other charges, drug distribution for other than legitimate medical purposes.[150] Dr. Sabean was convicted after writing prescriptions for the schedule IV controlled substances Ambien, Lunesta, and Xanax for his daughter, who lived in Florida, while Dr. Sabean remained in Maine.[151] Dr. Sabean did not dispute that he prescribed his daughter these medications, or that he knew that they were controlled substances.[152] However, he argued at trial and on appeal that treatment of family members by physicians did not rise to drug distribution without a legitimate medical purpose.[153]

In a motion *in limine* to exclude the testimony of the government's medical

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[148] Silverglate, *supra* note 26.

[149] McKee, *supra* note 121.

[150] Press Release, Dep't of Justice, U.S. Attorney's Office, Dist. of Me., Falmouth Doctor Sentenced to Two Years for Tax Evasion, Illegal Drug Distribution and Health Care Fraud (Apr. 26, 2017) https://www.justice.gov/usao-me/pr/falmouth-doctor-sentenced-two-years-tax-evasion-illegal-drug-distribution-and-health-care [https://perma.cc/4GQC-ZMBE] (note: some documents related to this case involve descriptions of sexual abuse).

[151] United States v. Sabean, 885 F.3d 27, 33, 46 (1st Cir. 2018).

[152] *Id.* at 46.

[153] *Id.* at 46-48.

expert, Dr. Sabean noted that the Maine Board of Licensure in Medicine's regulations did not prohibit him from treating family members or prescribing them controlled substances.[154] He argued that allowing the expert to testify as to the American Medical Associations Code of Ethics, which state that a physician may not treat family members except in emergency situations, had "the strong potential to confuse the jury as to the mens rea required in this case. Because the danger of such confusion substantially outweighs the probative value of a description of such standards, testimony as to such standards [must be] excluded."[155]

Dr. Sabean did not prevail on his motion *in limine* to exclude the expert opinion regarding the AMA ethical guidelines.[156] On appeal, the First Circuit, in upholding the lower court ruling, noted that:

> There is no pat formula describing what proof is required to ground a finding that a defendant acted outside the usual course of professional practice. Rather, inquiring courts must approach the issue on a case-by-case basis and sift the evidence in a given case to determine whether a specific set of facts will support a guilty verdict. In conducting this tamisage, testimony from a medical or pharmacological expert may be helpful—but such expert testimony is not a sine qua non to a finding of guilt. Jurors, of course, may draw on their everyday experience, and they can be expected to have some familiarity with how doctors care for patients. It follows, we think, that jurors may infer bad faith from conduct that is commonly understood to be plainly unprofessional.[157]

While not specifically an opioid crime, the path that led to Dr. Sabean's conviction is indicative of the perils faced by physicians prescribing controlled substances, especially when they are older and rural. Dr. Sabean's conviction for acts which, while inadvisable, are at best ethically suspect,[158] rested in the hands of jurors who were tasked with drawing on their own non-professional perceptions about how doctors should act. While jurors are advised that the standard for prescription without a legitimate purpose is higher than a malpractice standard, they are given little guidance as to what that higher standard might be. Meanwhile, Dr. Sabean was incarcerated for two years, his medical practice shuttered and employees let go, and his patients were left without the benefit of an experienced and respected physician whom some of them had seen for over thirty years.[159]

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[154] Defendant's Motion in Limine to Exclude Certain Testimony of Gary Hatfield, M.D. at 8-9, United States v. Sabean, No. 2:15-CR-175-GZS (D. Me. Oct. 5, 2016).

[155] *Id.* at 9-10 (quoting United States v. Yoon, No. CR 11-00922 B DDP 9, 2014 WL 5023100, at *2 (C.D. Cal. Oct. 8, 2014)).

[156] Order on Defendant's Motion in Limine to Exclude Certain Testimony of Gary Hatfield, M.D. at 2-3, *Sabean*, No. 2:15-cr-175-GZS (D. Me. Oct. 18, 2016).

[157] *Sabean*, 885 F.3d at 46-47 (citations omitted).

[158] *See* Frederick M. Chen et al., *Role Conflicts of Physicians and Their Family Members: Rules But No Rulebook*, 175 W. J. MED. 236, 236 (2001) (noting that "[c]onflicting rules of appropriate conduct, compounded by the inadequacies of modern health care, make the role of physician-family member especially challenging. The medical profession needs a clearer, more trenchant understanding of this role.").

[159] *See, e.g.,* Defendant's Memorandum of Law in Aid of Sentencing at Exhibit Q, *United States v. Sabean*, No. 2:15-CR-175-GZS (D. Me. Apr. 19, 2017) ("I have had the privilege of knowing Dr. Sabean since 1995, as one of his patients. I have always been informed, treated conservatively, and have received outstanding and effective care for the past twenty-two years.");

E. Solutions

The "without a medical purpose" element as it stands is difficult for both physicians and juries to comprehend. One means of clarifying the element would be to administratively codify the opioid guidelines published by the CDC, and to set similar guidelines with regard to other controlled substances. While the AMA has criticized the CDC opioid guidelines for setting the maximum opioid dosage levels too low for some patients with chronic pain, physicians would have the security of a bright-line rule which clearly states the threshold for criminal liability.

Alternatively, Congress could draft legislation that removes physicians from the scope of section 841(a) by creating a separate criminal statute tailored specifically to physicians who overprescribe controlled substances. As it stands, a clunky statutory mechanism prohibits everyone, including physicians, from distributing controlled substances, and then exempts those physicians from criminal liability when they register with the Attorney General and distribute the substances for a legitimate medical purpose. Congress could instead pass legislation which affirmatively states that registered physicians are authorized to distribute controlled substances, while also setting out a set of specific instances where distribution is prohibited–such as when a certain dosage or number of prescriptions are prescribed or when the physician knowingly prescribes controlled substances to a patient known to abuse or sell the substances.

Investigating, indicting, and convicting a physician for controlled substance distribution presents a number of highly scientific considerations that make prosecuting physicians distinct from prosecuting civilians. While currently judges and juries are tasked with deciding when distribution of controlled substances by a physician is without a legitimate medical purpose, Congress is the body that is best equipped to study and hear testimony on technical medical issues.

Finally, federal prosecutors could move away from prosecuting individual physicians and simply instruct the DEA to inform state medical licensing boards about suspicious or problematic prescribing practices by doctors. Medical licensing boards have the power to suspend or revoke physicians' medical licenses, which ultimately can have the effect of removing a doctor who is overprescribing opioids from medical practice without subjecting these physicians to the loss of liberty that typically results from a federal criminal conviction or guilty plea.

III. ALTERNATIVES TO PROSECUTING PHYSICIANS UNDER SECTION 841(A) AS A MEANS OF ADDRESSING THE OPIOID CRISIS

While criminal prosecutions of physicians can be improved, ultimately, prosecuting physicians is not the most effective means of targeting the root causes

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id. at Exhibit R ("If Dr. Sabean serves jail time, he will not be the only one who suffers. Not only will thousands of patients lose a great dermatologist, his employees will lose a great boss and friend."); *id.* at Exhibit S ("Professionally, Joel was our family dermatologist for over thirty years. He is a special gem in this area."); *id.* at Exhibit T ("Over approximately the past forty-three years that I have known him, Dr. Sabean has taken care of my entire family . . . Dr. Sabean saved my father's life. . . . I urged him to see Dr. Sabean, who, upon examining my father, found melanoma in two places.").

of the opioid epidemic. Even without the specter of criminal prosecution, physicians who overprescribe controlled substances face the much lower bar that is required for state medical boards to revoke their professional licenses and deprive them of their abilities to practice medicine and make a living, as well as the (theoretically) lower bar of civil medical malpractice suits by the families of victims of over prescription. While often prosecutors target individual physicians, the massive corporations at the root of the opioid crisis are a better target for the legal system.

A. The Origins of the Opioid Crisis

OxyContin, the drug at the heart of the opioid crisis, was first approved by the Food and Drug Administration in 1995.[160] The drug was developed by Purdue Frederick, a pharmaceutical company owned by a trio of wealthy brothers—Mortimer, Raymond, and Arthur Sackler.[161] Purdue Pharma, the marketing arm of Purdue Frederick, stated from the outset that "the risk of addiction when taking an opioid is one-half of 1 percent."[162]

The idea that OxyContin, a synthetic derivative of opium, could have a low risk of addiction was at odds with history. Opium and its derivatives, including morphine and heroin, had been known sources of addiction for centuries.[163] After the Civil War, roughly a hundred thousand veterans became addicted to the morphine that doctors routinely prescribed to treat their injuries.[164] At the end of the nineteenth century, heroin, which is twice as powerful as morphine, and initially believed to be nonaddictive, was discovered and soon sold all over the world, lacing everything from cough drops to baby-soothing syrups.[165] Within a decade, however, heroin's devastating addictive qualities were recognized, and by 1924, manufacturing it was officially illegal in the United States.[166]

Despite the history of opiate addiction in the United States, in the mid-1990s prescribing OxyContin was marketed as "the moral, responsible, and compassionate thing to do—and not just for dying people . . . but also for folks with moderate back injuries, wisdom-tooth surgery, bronchitis, and temporomandibular joint disorder."[167] OxyContin hit the market just as the medical community began to treat pain as a vital sign in need of greater focus and treatment, and Purdue seized on this mindset in their marketing schemes.[168] One Virginia emergency medicine doctor stated that, in response to the newfound focus on pain scales and pain relief, "[e]very single physician I knew at the time was told to be much more serious about making pain a priority . . . . All it did was drive up our opioid prescribing without really

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[160] BETH MACY, DOPESICK: DEALERS, DOCTORS, AND THE DRUG COMPANY THAT ADDICTED AMERICA 20 (2018).
[161] *Id.*
[162] *Id.* at 20-21.
[163] *Id.* at 20-26.
[164] *Id.* at 22.
[165] *Id.* at 24.
[166] *Id.* at 25.
[167] *Id.* at 27.
[168] *Id.* at 27-28.

understanding the consequences of what we were doing."[169]

Purdue realized early on that OxyContin was most successful in small, rural towns.[170] It purchased data to figure out which physicians prescribed the most of their competitors' drugs, and sent representatives to pitch OxyContin and its alleged safe and potent pain relief.[171] Representatives were known to gift doctors lunches, dinners, golf outings, and numerous branded products in order to promote OxyContin.[172] Often, these were "impressionable young doctors, fresh meat with a lifetime of prescribing ahead."[173] By 2001, sales-rep bonuses topped forty billion dollars (up from one million dollars in 1996).[174] Representatives routinely handed out "starter coupons" giving patients free thirty-day supplies of OxyContin, and Purdue Pharma paid for over five thousand doctors, nurses, and pharmacists to attend pain management conferences in resorts from Florida to Arizona during the first five years of the drug's existence.[175] All this as opioid-related overdoses, robberies, violent crimes, and deaths were already beginning to skyrocket in rural communities from Virginia to Maine, as well as in large cities and suburbs across the East Coast, Deep South, and Southwest.[176]

Purdue claimed that it was unaware of OxyContin's potential for abuse until 2000. However, as early as 1995, when it submitted its New Drug Application with the Food and Drug Administration (FDA), it was clear that the company knew of the drug's dark downsides; that the drug could be crushed up and snorted, leading to its immediate (instead of controlled) release; that, when liquified and injected, sixty-eight percent of the drug was recoverable; and that in patient trials, several patients had experienced symptoms of withdrawal.[177] Despite these findings, the FDA allowed Purdue to market OxyContin's long-acting formulation as "believed to reduce" its addictive nature.[178] In 1998, a study and accompanying editorial published in The Journal of the Canadian Medical Association found that, in reality, drug users and dealers "coveted" long-acting opioids like OxyContin.[179] While Purdue knew of this study, it did not disclose it to the FDA or to its sales reps, whom the company continued to use to push their narrative of the drug's non-addictive nature.[180] By 2001, when the addictive nature of OxyContin had become more widely known, Richard Sackler—the son of Raymond Sackler and the then-president of Purdue Pharma—wrote an email advising that the company push the blame onto

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[169] *Id.* at 28.
[170] *Id.* at 31.
[171] *Id.* at 32.
[172] *Id.* at 33-34.
[173] *Id.* at 34.
[174] *Id.* at 47.
[175] *Id.*
[176] *Id.* at 44, 58.
[177] *Id.* at 63.
[178] Barry Meier, *Origins of an Epidemic: Purdue Pharma Knew Its Opioids Were Widely Abused*, N.Y. TIMES (May 29, 2018), https://www.nytimes.com/2018/05/29/health/purdue-opioids-oxycontin.html?action=click&module=RelatedLinks&pgtype=Article [https://perma.cc/KGT7-GZ66].
[179] *Id.*
[180] *Id.*

the very consumers who had unwittingly become addicted to his company's drug, stating that "[w]e have to hammer on abusers in every way possible. . . . They are the culprits and the problem. They are reckless criminals."[181] Even in 2007, when Purdue Pharma had already entered into one settlement with the Justice Department and attorneys general in other states were suing, Purdue continued to push OxyContin onto veterans and the elderly, downplaying the risks of addiction.[182]

Drug distributors—who distribute and track medications from warehouses to healthcare providers—also played a heavy role in the opioid crisis.[183] Distributors such as Cardinal Health, McKesson, AmerisourceBergen, and Rochester Drug Co-Operative have been alleged to have shipped oxycodone to pharmacies despite knowing that the prescriptions were suspicious.[184] Despite being legally required to monitor suspicious opioid orders, the three largest distributors are alleged to not have had any meaningful programs in place for the first decade of the opioid crisis.[185]

B. Legal Strategies for Holding Pharmaceutical Companies Responsible

To date, there have been numerous legal battles designed to hold Purdue Pharma and other opioid companies accountable for their role in the opioid crisis. Many of these battles remain ongoing. Because of their potential to gain monetary funds for opioid treatment, their insight into the roots of the opioid crisis, and the control they offer the federal government over opioid manufacturers and distributors, these options are more productive than criminal charges levied against individual physicians.

1. Federal Multidistrict Litigation

Over 1500 cases brought on behalf of cities, counties, tribes, hospitals, third-party payers, and individuals against roughly thirty defendants—including opioid manufacturers such as Purdue Pharma and Cardinal Health and retailers like CVS—were consolidated by the Judicial Panel on Multidistrict Litigation and assigned to Judge Dan Aaron Polster of the Northern District of Ohio in January of 2018. Initially, Judge Polster stated that he hoped to see the cases settled within a year, declaring that "[w]e don't need briefs and we don't need trials."[186] However, Judge

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[181] Barry Meier, *Sacklers Directed Efforts to Mislead Public About OxyContin, Court Filing Claims*, N.Y. TIMES (Jan. 15, 2019), https://www.nytimes.com/2019/01/15/health/sacklers-purdue-oxycontin-opioids.html?action=click&module=RelatedLinks&pgtype=Article [https://perma.cc/L8FW-NPLP].

[182] Jamie Satterfield & Kristi L. Nelson, *OxyContin Maker Used Subterfuge to Sell Public on Safety, Targeted Veterans, Elderly, Suit Says*, KNOX NEWS (July 16, 2018), https://www.knoxnews.com/story/news/crime/2018/07/16/oxycontin-purdue-pharma-used-subterfuge-targeted-veterans-elderly-suit-says/784193002/ [https://perma.cc/5LTW-LVAX].

[183] Danny Hakim et al., *The Giants at the Heart of the Opioid Crisis*, N.Y. TIMES (Apr. 22, 2019), https://www.nytimes.com/2019/04/22/health/opioids-lawsuits-distributors.html?smid=nytcore-ios-share [https://perma.cc/LSF5-ZTZE].

[184] *Id.*

[185] *Id.*

[186] Amelia McDonell-Parry, *Opioid Lawsuits Heat Up Across America*, ROLLING STONE (Jan. 31, 2019), https://www.rollingstone.com/culture/culture-news/opioid-epidemic-lawsuits-purdue-pharma-786813/ [https://perma.cc/B5CM-48N8].

Polster later changed course, and a bellwether trial for three consolidated lawsuits was set to take place in October of 2019.[187] Hours before opening arguments were scheduled to begin, however, the two Ohio counties and four drug companies set to battle in that trial announced that they had reached a $260-million settlement.[188] The settlement is likely to play a major role in determining the resolution of the many remaining lawsuits and may lay the groundwork for a global settlement.[189]

2. State Attorney General Lawsuits

The multidistrict litigation is only one aspect of the legal troubles facing opioid manufacturers and distributors. Attorneys general in many states have chosen to file their own independent lawsuits rather than join the consolidated cases pending in Ohio, and in total there are over three-hundred pending opioid-related cases in state courts.[190] On March 26, 2019, the State of Oklahoma reached a $270-million settlement with Purdue Pharma and the Sackler family in a lawsuit over their role in the opioid crisis.[191] In Massachusetts, the Attorney General filed a similar lawsuit against Purdue and the Sacklers, alleging that the company continued to market OxyContin aggressively despite knowing of rising overdose deaths.[192] Purdue and the Sacklers are not the only defendants in state lawsuits, which target a wide range of manufacturers, distributors, and individuals.[193]

3. Federal Criminal Charges

Until recently, the Justice Department has focused on criminal investigations of physicians, online drug networks, and illicit foreign opioid manufacturers, rather than on the manufacturers and distributors in the U.S. that created the opioid crisis.[194]

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[187] *Id.*

[188] Lenny Bernstein et al., *Last-Ditch Opioid Settlement in Ohio Could Open Door for Much Larger Deal*, WASH. POST (Oct. 21, 2019), https://www.washingtonpost.com/health/ohio-counties-drug-firms-reach-260m-settlement-averting-trial/2019/10/21/c9ac1dd4-f39f-11e9-ad8b-85e2aa00b5ce_story.html [https://perma.cc/CP5J-VJBM].

[189] *Id.*

[190] Christine Vestal, *Pay Attention to This Little-Noticed Opioid Lawsuit in Oklahoma*, PEW (Feb. 14, 2019), https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2019/02/14/pay-attention-to-this-little-noticed-opioid-lawsuit-in-oklahoma [https://perma.cc/7L7Y-D8N8].

[191] Jan Hoffman, *Purdue Pharma and Sacklers Reach $270 Million Settlement in Opioid Lawsuit*, N.Y. TIMES (Mar. 26, 2019), https://www.nytimes.com/2019/03/26/health/opioids-purdue-pharma-oklahoma.html?smid=nytcore-ios-share [https://perma.cc/W6HZ-ZAXV].

[192] Christine Willmsen & Martha Bebinger, *Massachusetts Attorney General Implicates Family Behind Purdue Pharma in Opioid Deaths*, NPR (Jan. 16, 2019), https://www.npr.org/sections/health-shots/2019/01/16/685692474/massachusetts-attorney-general-implicates-family-behind-purdue-pharma-in-opioid- [https://perma.cc/QAZ8-AYDK].

[193] Nicole Fisher, *Opioid Litigation on Par to Become Largest Civil Litigation Agreement in U.S. History,* FORBES (Oct. 18, 2018), https://www.forbes.com/sites/nicolefisher/2018/10/18/opioid-lawsuits-on-par-to-become-largest-civil-litigation-agreement-in-u-s-history/#54e572967fb4 [https://perma.cc/7PL3-7Z7C].

[194] Joseph Tanfani, *Justice Department to Target Opioid Manufacturers and Distributors in a New Push to Curb Deadly Epidemic*, L.A. TIMES (Feb. 27, 2018), https://www.latimes.com/politics/la-na-pol-opioid-manufacturers-20180227-story.html [https://perma.cc/GL36-EC5H].

In 2007, after a four-year investigation by the Justice Department discovered evidence that "Purdue Pharma knew about 'significant' abuse of OxyContin in the first years after the drug's introduction in 1996 and concealed that information," federal prosecutors recommended felony indictments for three Purdue Pharma top executives on charges including conspiracy to defraud the United States.[195] However, top Justice Department officials instead reached a settlement with Purdue and its executives in which the company paid approximately $600 million in fines and three of its top executives pleaded guilty to criminal "misbranding" violations and agreed to pay thirty-four million dollars in fines.[196]

Since the 2007 settlement, there have been few federal cases against opioid manufacturers or distributors. However, the tide appears to be shifting, as federal prosecutors appear to be increasing their efforts against drug manufacturers and distributors. In May 2019, five executives of Insys Therapuetics, Inc. were convicted of federal racketeering charges by a Boston federal jury.[197] The United States Attorney's Office for the District of Massachusetts successfully alleged that founder and former Chief Executive Officer John Kapoor bribed doctors to prescribe high doses of Subsys—an opioid that is one hundred times stronger than morphine and highly addictive—to patients who did not need it.[198] Insys then had employees call insurance companies while pretending to be from doctors' offices, fabricating diagnoses in order to get coverage for the Subsys prescriptions.[199] At trial, jurors were shown internal spreadsheets that Insys made to track the amount of money it paid to each doctor and the amount the company made from each doctor's prescriptions.[200]

Moreover, on April 23, 2019, the Justice Department announced that the United States Attorney's Office for the Southern District of New York had brought federal criminal charges against Rochester Drug Co-Operative ("RDC"), which is one of the ten largest drug distributors in the country, as well as two of the RDC's former officers.[201] The charges included unlawful distribution of oxycodone and fentanyl as well as conspiracy to defraud the DEA, and the Government also brought a civil

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[195] Barry Meier, *Origins of and Epidemic: Purdue Pharma Knew Its Opioids Were Widely Abused*, N.Y. TIMES (May 29, 2018), https://www.nytimes.com/2018/05/29/health/purdue-opioids-oxycontin.html [https://perma.cc/5HL4-H4EJ].

[196] For more information, *see* German Lopez, *The Case for Prosecuting the Sacklers and Other Opioid Executives*, VOX (Oct. 10, 2019), https://www.vox.com/policy-and-politics/2019/10/10/20881636/sacklers-purdue-opioid-epidemic-prison-prosecution-criminal-investigation [https://perma.cc/8N34-YTRD].

[197] Ashley Turner, *Insys Therapeutics Founder, Former Executives Found Guilty in Criminal Fentanyl Bribery Case*, CNBC (May 2, 2019), https://www.cnbc.com/2019/05/02/insys-therapeutics-former-executives-found-guilty-in-criminal-opioid-case.html [https://perma.cc/BN97-RBND].

[198] Gabrielle Emanuel, *Criminal Trial of Opioid-Peddling Drug Company Execs Goes to the Jury*, NPR (April 5, 2019), https://www.npr.org/2019/04/05/710454888/criminal-trial-of-opioid-peddling-drug-company-execs-goes-to-the-jury [https://perma.cc/5F7D-XVHM].

[199] *Id.*

[200] *Id.*

[201] *Manhattan U.S. Attorney and DEA Announce Charges Against Rochester Drug Co-Operative and Two Executives for Unlawfully Distributing Controlled Substances*, U.S. DEP'T OF JUSTICE (April 23, 2019), https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-and-dea-announce-charges-against-rochester-drug-co-operative-and [https://perma.cc/9Q3U-354F].

suit against RDC for their failure to report suspicious controlled substance orders to the DEA.[202]

Although the charges levied against RDC were severe, the Government also announced that it had reached an agreement with RDC "under which RDC agreed to accept responsibility for its conduct by making admissions and stipulating to the accuracy of an extensive Statement of Facts, pay a 20 million dollar penalty, reform and enhance its Controlled Substances Act compliance program, and submit to supervision by an independent monitor."[203] The government agreed that if RDC remained in compliance with the agreement, it would defer prosecution for five years and then dismiss the charges.[204]

The two former RDC officials, William Pietruszewski and Laurence F. Doud III, were charged with illegal narcotics distribution in violation of 21 U.S.C. section 841(a)(1), as well as conspiracy to defraud the United States.[205] Mr. Pietruszewski was also charged with failure to file suspicious order reports with the DEA.[206] The charges against Mr. Doud remain pending, while Mr. Pietruszewski pled guilty to the charges against him, pursuant to a cooperation agreement.[207]

C. Why, Despite Their Limits, These Options Offer Greater Benefits than Prosecuting Individual Physicians

Litigation against drug manufacturers and distributors, alone, will not solve America's opioid epidemic. However, particularly in contrast with prosecuting doctors, there are far greater benefits to pursuing both civil and criminal litigation against drug manufacturers and distributors than against individual physicians. Litigation against drug companies has the potential to bring about large-scale change in the current treatment of opioid users and in the future of drug approval, marketing, and regulation.

The first and most obvious benefit of going after drug companies is money. In many of the cases noted above, pharmaceutical manufacturers and distributors have reached massive settlements with both state governments and the federal government. For instance, in Oklahoma, over $100 million of the state's $270 million settlement with Purdue is earmarked for a new addiction treatment and research center at Oklahoma State University in Tulsa.[208] Opioid litigation has the potential to be on par with the Big Tobacco litigation of the 1990s, which resulted in the largest civil litigation settlement agreement in U.S. history.[209] While plaintiffs

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[202] *Id.*

[203] *Id.*

[204] *Id.*

[205] *Id.*; Information, United States v. Pietruszewski, 19 Cr. (WHP) (S.D.N.Y.); Seal Indictment, United States v. Doud, 19 Cr. 285 (S.D.N.Y. Apr. 22, 2019). Obviously, there are issues with charging pharmaceutical executives with this imprecise statute similar to the issues outlined *supra* in this Comment, however, those issues are beyond the scope of this Comment.

[206] *Manhattan U.S. Attorney and DEA Announce Charges Against Rochester Drug Co-Operative and Two Executives for Unlawfully Distributing Controlled Substances, supra* note 201.

[207] *Id.*

[208] Jan Hoffman, *supra* note 191.

[209] Fisher, *supra* note 193.

involved in litigation against opioid manufacturers face the additional legal burden of proving that the drugs, which were FDA approved, were used as directed and still caused harm, they also have the benefit of decades of improvement in health records and pharmacy records, as well as the precedent set by the Big Tobacco litigation.[210] Like the Master Settlement Agreement reached by the states and the Big Tobacco companies, and like the settlement agreement reached in Oklahoma, litigation against pharmaceutical manufacturers and distributors could ultimately result in those companies footing the bill for large-scale opioid addiction cessation treatment, research, and awareness.[211]

Criminal and civil litigation against pharmaceutical companies also give the public far greater insight into the root causes of the opioid epidemic. Barry Meier, who has covered the opioid epidemic for the *New York Times* for seventeen years, noted that a downside to settling cases with opioid companies is that lawsuits are often ended quickly, before discovery has a chance to truly develop, and that even when information regarding companies' knowledge of the addictive nature of opioids is discovered, it is often subject to confidentiality agreements reached as part of the settlements.[212] If cases against opioid companies go to trial, however, important information about the history of the opioid epidemic could be revealed, which could impact the future of how governments approve and regulate drugs, as well as how companies test, market, and sell them.[213]

Civil and criminal actions against pharmaceutical companies by the government can also allow for greater government control over specific companies that have acted wrongly. While the federal government already has extensive regulatory control over drug companies, agreements between the government and drug companies that come about as a result of lawsuits can bring bad actor companies under even greater scrutiny. For instance, the recently deferred prosecution agreement between the government and Rochester Drug Co-Operative, requiring reform and expansion of the company's Controlled Substances Act compliance program and independent supervision, is just one example of how prosecuting drug companies can give the federal government tighter control over companies that are known to have harmed the public with addictive and dangerous drugs.

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[210] *Id.*

[211] *See* TOBACCO CONTROL LEGAL CONSORTIUM, THE MASTER SETTLEMENT AGREEMENT: AN OVERVIEW https://www.publichealthlawcenter.org/sites/default/files/resources/tclc-fs-msa-overview-2015.pdf [https://perma.cc/QT7U-SEBN]. One major caveat to this point is that in the fall of 2019 Purdue filed for Chapter 11 bankruptcy, which has temporarily paused lawsuits against Purdue in anticipation of working out the nearly 2600 suits against the company. Associated Press, *Judge Pauses Lawsuit Against Purdue Pharma and its Owners*, L.A. TIMES (Oct. 11, 2019), https://www.latimes.com/business/story/2019-10-11/judge-halt-lawsuits-purdue-pharma [https://perma.cc/25GJ-U4KV].

[212] Barry Meier, *Opioid Makers Are the Big Winners in Lawsuit Settlements*, N.Y. TIMES (Dec. 26, 2018), https://www.nytimes.com/2018/12/26/opinion/opioids-lawsuits-purdue-pharma.html [https://perma.cc/3CXP-5DNV]; *PBS News Hour: Will Drug Companies be Held Accountable for America's Opioid Epidemic*, PBS.ORG (Jan. 1, 2019), https://www.pbs.org/newshour/show/will-drug-companies-be-held-accountable-for-americas-opioid-epidemic [https://perma.cc/6RMX-BNAW].

[213] *PBS News Hour: Will Drug Companies be Held Accountable for America's Opioid Epidemic, supra* note 212.

CONCLUSION

America's opioid epidemic is complex and challenging, and it will not be overcome by any one policy or strategy. Experts recommend a number of intertwined strategies to combat this disease of despair, including stricter prescribing measures; expansion of alternative treatment for current sufferers of chronic pain who rely on opioids; expanded addiction treatment; needle exchange programs and supervised injection sites; increased access to naloxone; and, perhaps most fundamentally, changes to the way communities address physical, emotional, economic, and social well-being.[214] Litigation in any form can only look backward in an attempt to hold wrongful parties responsible and gain knowledge from past missteps.

The prosecution of physicians is simply one small piece of the complicated puzzle that is the opioid crisis. It may seem that clarifying the means by which doctors are prosecuted is an academic exercise in the face of a real and critical epidemic. However, the circuit split on the elements required to be alleged in indictments against doctors, as well as the larger issues with defining the without a legitimate medical purpose element, have real ramifications not only on physicians, but on communities who depend on doctors for needed healthcare. Congress and the courts should take care to clarify and redefine the type of conduct that rises to criminality among physicians, who often struggle to walk the line between providing compassionate medical care and overprescribing dangerous drugs. Moreover, state and federal governments who seek to hold people and entities responsible for the opioid crisis should look beyond individual medical practitioners, and instead focus on the drug companies and their executives whose direct and knowledgeable actions brought this epidemic into being. Holding the proper parties responsible for the opioid crisis is one of many steps the government can take in helping the nation to heal.

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[214] German Lopez, *How to Stop the Deadliest Drug Overdose Crisis in American History*, VOX (Dec. 21, 2017), https://www.vox.com/science-and-health/2017/8/1/15746780/opioid-epidemic-end [https://perma.cc/8BGL-NTDD].